Hecho Relevante

A LA COMISIÓN NACIONAL DEL MERCADO DE VALORES

Madrid, 24 de octubre de 2017

En cumplimiento de lo previsto en el artículo 228 de la Ley del Mercado de Valores y en el artículo 17 del Reglamento (UE) nº 596/2014 del Parlamento Europeo y del Consejo, de 16 de abril, sobre abuso de mercado, y como continuación al hecho relevante número 249265 del pasado 7 de marzo de 2017, Laboratorios Farmacéuticos ROVI, S.A. ("ROVI" o la "Sociedad") envía y hace pública la presentación adjunta referente a la actualización de la Fase III-Prima 3 del proyecto de Risperidona ISM® de ROVI (DORIA®), presentación que se distribuirá en el día de hoy y a la que se podrá acceder a través de la página web de la Sociedad. Asimismo, ROVI mantendrá hoy una reunión con analistas e inversores para actualizar la información sobre este proyecto.

D. Juan López-Belmonte Encina

Consejero Delegado

Laboratorios Farmacéuticos ROVI, S.A.

DORIA®

The fast onset of action long-acting injectable of risperidone

Based on our ISM® patented technology

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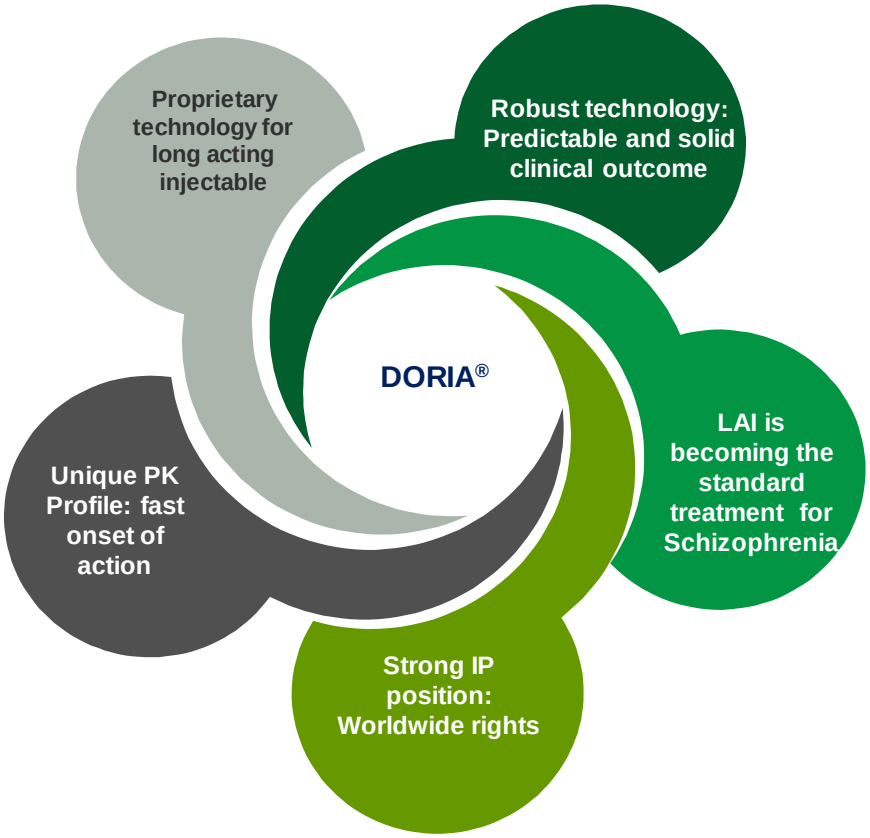
Index

Executive Summary

- ROVI is going through an important moment in its history launching our biosimilar of enoxaparin in Europe and beginning one Phase III and other Phase I in our R&D pipeline.
- ROVI has begun a Phase III study for a long-acting injectable (LAI) based in the ISM® technology patented by ROVI, to treat schizophrenia called DORIA® (previously Risperidone ISM®).
- Schizophrenia diagnosed disorders affects around 3Mn patients* in US and Europe, and although it has no cure, there are effective treatments to control symptoms.
- These treatments use Second-Generation of Antipsychotics (SGA) medications with a predictable efficacy and safety profile, and risperidone is the most used active principle.
- Long-acting injectable (LAI) is becoming the goal standard for schizophrenia compared to oral treatments, and ROVI has studied the market deeply with Kantar Consulting and IMS before taking important decisions.
- ROVI has developed DORIA®, and expects a good evolution in Phase III, as the Active Principle is one of the most prescribed for schizophrenic patients (risperidone) and ISM® technology has been proved in Phase I&II studies.
- With DORIA®, ROVI is aiming to play a relevant role in the US and Europe Schizophrenia LAIs market, with an estimated total value in 2021 of $3.4Bn ($2.5Bn in US and $930Mn Top-5 Europe).

* Source: IMS Midas

Executive Summary: DORIA® Strategic Drivers

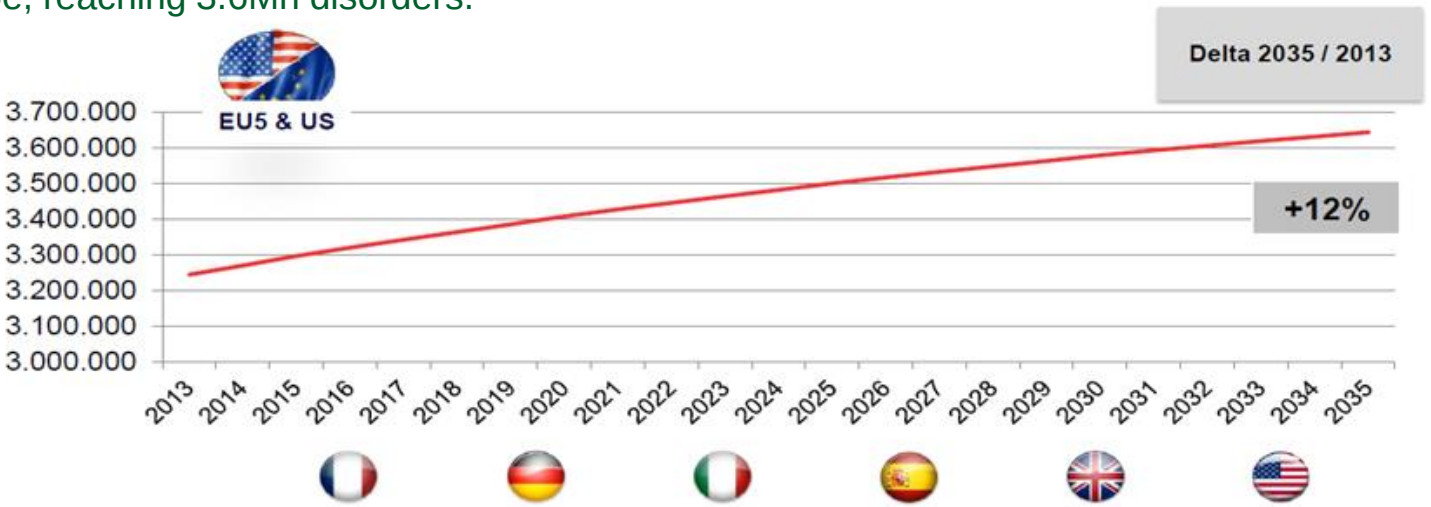


- DORIA® is a long acting injectable (LAI) based in the ISM® technology developed by ROVI.
- LAI is becoming the goal standard for Schizophrenia.
- DORIA® has an good pharmacological profile providing a rapid onset allowing a once monthly injection without oral supplementation and loading dose.
- One monthly represents a fully medically supervised patient: eradicates all potential issues that may arise with a oral product.
- A monthly injection provides a better control of patients avoiding relapses.
- One monthly ensures a relapse rate improvement which on a pharmacoeconomic basis that justifies a cost effective of LAIs.

Schizophrenia and antipsychotics

Epidemiology of Schizophrenic Disorders

- Schizophrenia is a complex illness with no cure, although effective treatments are available to control symptoms and reduce disability.
- In 2013, 1.7Mn schizophrenic disorders* were diagnosed in US and 1.6Mn were diagnosed in Top 5 Europe.
- From 2013 to 2035**, schizophrenia disorders are expected to grow 19% in US, and 4% in Top 5 Europe, reaching 3.6Mn disorders.

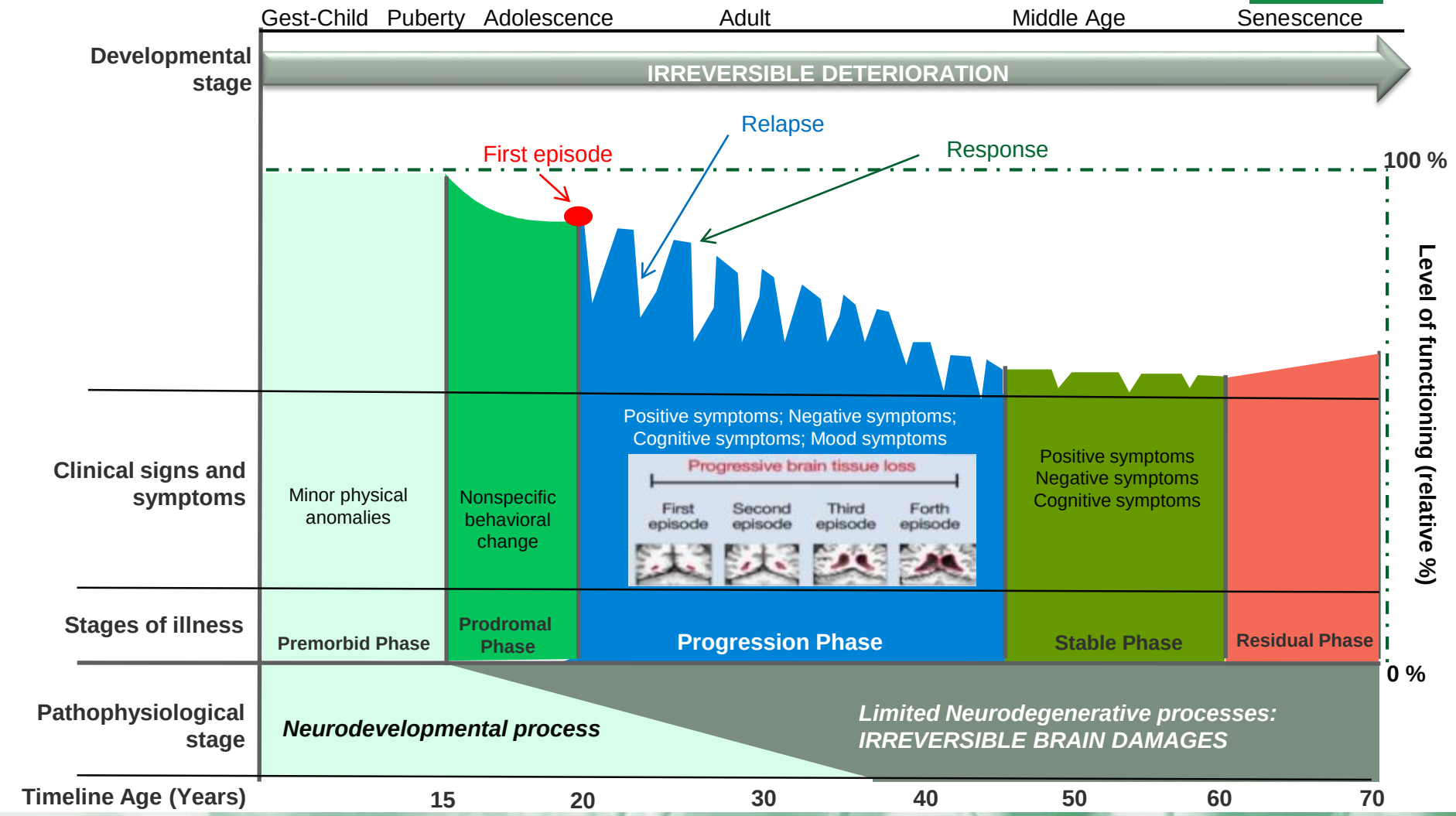


2013	306.123	404.539	296.627	226.407	302.622	1.707.251
2035	338.587	389.175	302.773	230.553	342.479	2.040.039
Delta	11%	-4%	2%	2%	13%	19%

* Source: Wu EQ, Shi L, Birnbaum H, Hudson T, Kessler R. "Annual prevalence of diagnosed schizophrenia in the USA: a claims data analysis approach". Psychol Med. 2006 Nov;36(11):1535-1540. Epub 2006 Aug 15 / Standard curve fitting techniques were used with the age- and gender-specific data from this study to determine prevalence by 5 year age cohorts. A point estimate was applied to all years in the analysis / Tizón JL, Ferrando J, Artigue J, Parra B, Parés A, Gomà M, et al., "Neighborhood differences in psychoses: prevalence of psychotic disorders in two socially-differentiated metropolitan areas of Barcelona". Schizophr Res. 2009 Jul;112(1-3):143-148. Epub 2009 May 2.

** Source: Epidemiology data-Kantar Health Epi Database®

Course of Schizophrenia: A progressive disorder



Reference: Sheitman BB, Lieberman JA. The natural history and pathophysiology of treatment-resistant schizophrenia. J Psychiatr Res. 1998 (May-Aug);32(3-4):143-150

Nasrallah HA, Smeltzer DJ. Contemporary diagnosis and management of the patient with schizophrenia. 2nd ed. Newton, PA: Handbooks in Health Care CO; 2011

Schizophrenia's phases

ACUTE PHASE	STABILIZATION PHASE	STABLE PHASE
Treatment goals*		
• Prevent harm and control disturbed behavior. • Reduce psychosis and symptoms. • Determine and address the factors of the acute episode. • Effect a rapid return to the best level of functioning. • Develop an alliance with the patient and family. • Formulate short/long-term treatment plans • Connect the patient with appropriate aftercare in the community.	• Reduce stress on the patient. • Provide support to minimize the likelihood of relapse. • Enhance the patient's adaptation to life in the community. • Facilitate continued reduction in symptoms and consolidation of remission. • Promote the process of recovery.	• Sustain symptom remission or control. • Maintain or improve patient's level of functioning and quality of life. • Effectively treat increases in symptoms or relapses. • Continue monitoring for adverse treatment effects.
Considerations*		
• Pharma treatment should be initiated promptly • Selection of antipsychotics: frequently guided by the patient's previous experience (degree of symptom response, past experience of side effects, and preferred route of medication administration). • **Patients with recurrent relapses related to nonadherence are candidates for a long-acting injectable (LAI) antipsychotic medication.**	• Premature lowering of dose or discontinuation of medication during this phase may lead to a recurrence of symptoms and possible relapse.	• Antipsychotic medications substantially reduce the risk of relapse in the stable phase of illness and are strongly recommended.

* Source: Lehman AF, et al. American Psychiatric Association.; Steering Committee on Practice Guidelines.. Practice guideline for the treatment of patients with schizophrenia, second edition. Am J Psychiatry. 2004;161(2 Suppl):1-56.

Frequency of acute exacerbations in schizophrenic patients

At least one episode of acute exacerbation over 1st year

7 months | 8 months | 9 Months | 10 months | 11 months | 12 months | 13 months | 14 months | 15 months | 16 months | 17 months | 18 months

The incidence of acute episodes is particularly high in the 5 years after the initial episode with a cumulative first relapse rate of 81,9%; of those 78% will have a second relapse, and a further 86,2% of those will go on to have a third relapse*.

* Source: Kantar market study. Internal questionnaire to hey leaders opinion Base: Total physicians n=140. Q4. Thinking now about the (INSERT NUMBER FROM S4.1) patients with schizophrenia who have had at least one episode of acute exacerbation in the past year, according to your experience, please indicate how often on average a patient has an episode of acute exacerbation?

Heres et al (2014). Treatment of early episode in patients with schizophrenia: the role of long acting antipsychotics. European Psychiatry 29 S2 (2014) 1409-1413

Antipsychotic treatment

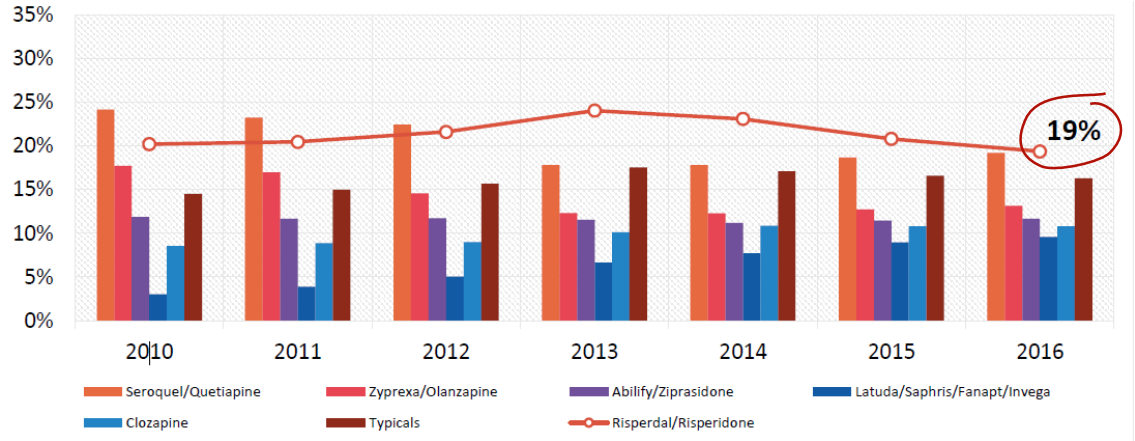
- Antipsychotic is a psychiatric medication that works by helping to restore the balance of certain natural substances in the brain (neurotransmitters).
- Antipsychotics are most frequently used for the following conditions: schizophrenia, schizoaffective disorder, bipolar disorder (acute mania and mixed episodes) and psychotic depression.
- Antipsychotic nonadherence is the most common reason for hospitalization*.
    - After first episode, if become no adherent: readmission risk 5 times higher in the first year.
- Additional consequences of nonadherence:
    - ✓ greater risk of comorbid substance use disorder,
    - ✓ poorer cognitive functioning,
    - ✓ reduced quality of life and increased rates of arrest, violence/aggression, victimization, and risk of suicide.
    - ✓ negative emotional and financial impact on families and caretakers
- **Nonadherence patients with recurrent relapses are candidates for a long-acting injectable (LAI) antipsychotic medication.**

* Source: Phan SV. Medication adherence in patients with schizophrenia. Int J Psychiatry Med. 2016;51(2):211-9

Second generation antipsychotics (SGA)

- The second-generation (atypical) antipsychotic (SGA) drugs promised enhanced efficacy and safety of first generation. This drugs may be administrated daily (oral) or monthly (injectable).
- The molecules used in the second-generation are risperidone, paliperidone, aripiprazole, olanzapine, ziprasidone.
- Risperidone* is one of the most common SGA used with evidence of efficacy in the treatment of acute episodes of schizophrenia.
- In 2016, it had 19% market share of total prescriptions in schizophrenia.

Share of total prescriptions in schizophrenia**



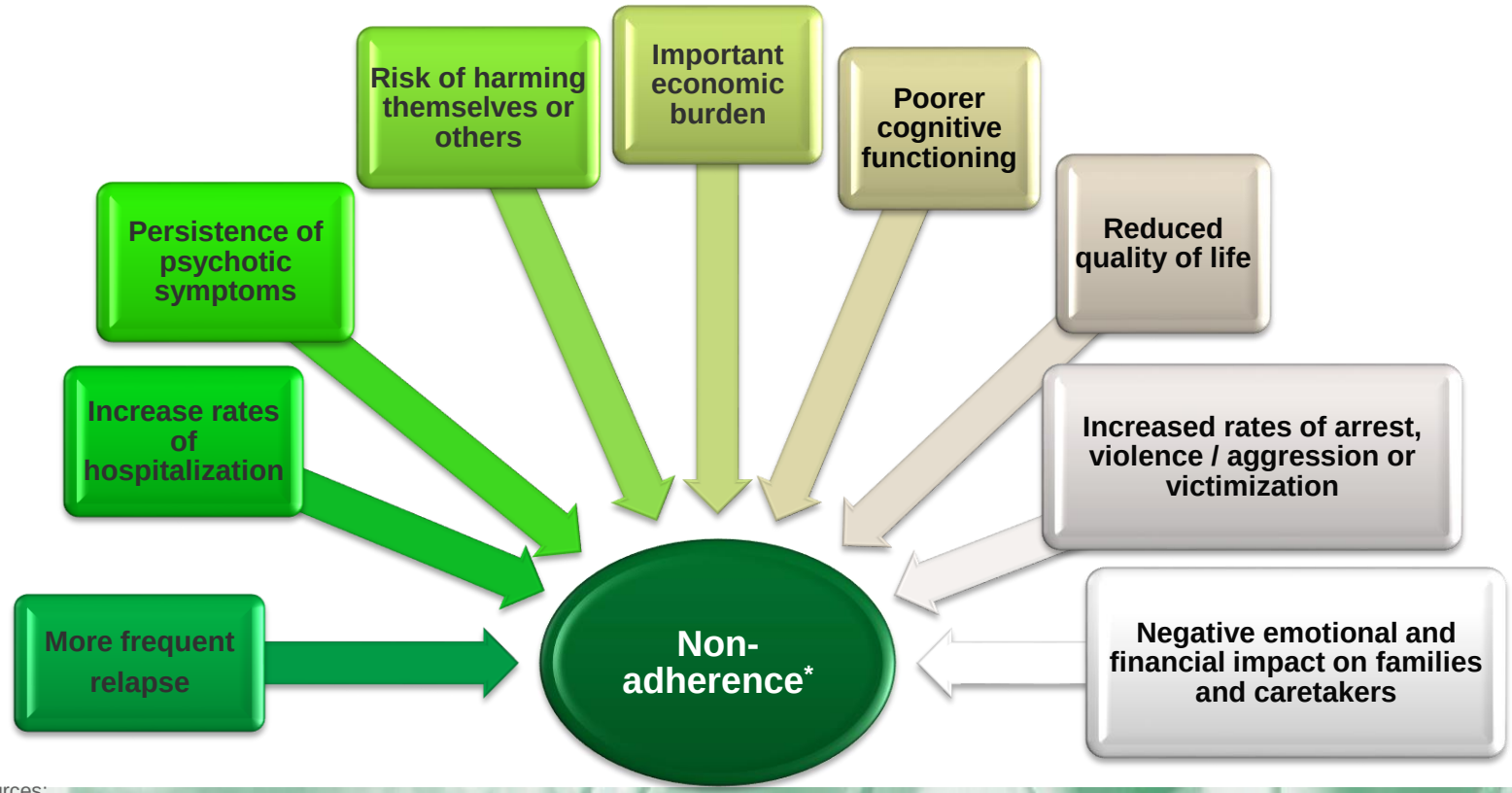
Compared to haloperidol, risperidone has demonstrated superior efficacy in the prevention of relapse in the maintenance phase of treatment, and has very well known safety profile.

* Source: Falkai P, et al; WFSBP Task Force on Treatment Guidelines for Schizophrenia. World Federation of Societies of Biological Psychiatry (WFSBP) guidelines for biological treatment of schizophrenia, Part 1: acute treatment of schizophrenia. World J Biol Psychiatry. 2005;6(3):132-91.
Lehman AF, et al. American Psychiatric Association.; Steering Committee on Practice Guidelines. Practice guideline for the treatment of patients with schizophrenia, second edition. Am J Psychiatry. 2004 Feb;161(2 Suppl):1-56.
** Source: IMS and Source Healthcare, MAT Apr 2016

Problem of Non-Adherence

- The development of new drug formulations that improve the pharmacokinetic profile and lengthen the dosing interval could contribute to increase the treatment adherence.

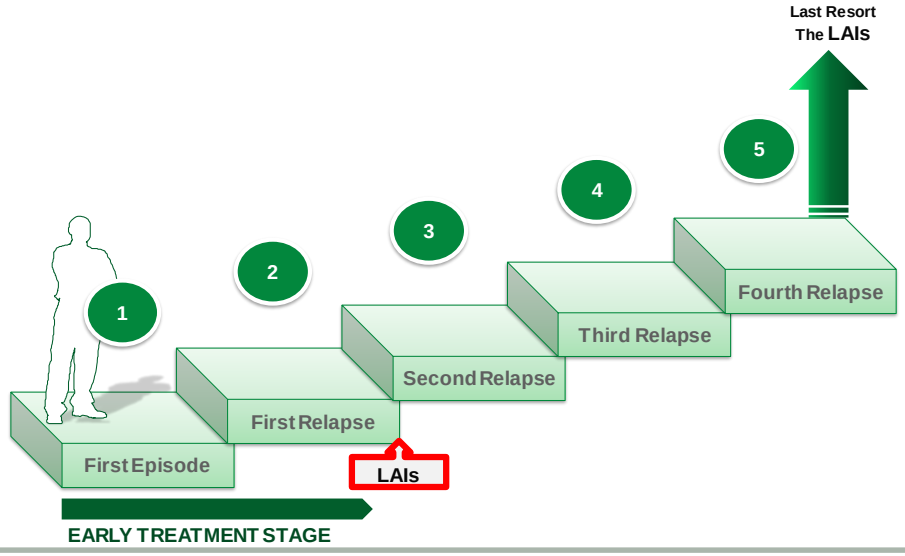
- The discontinuation rates of oral antipsychotics in chronic schizophrenia have been estimated to be as high as 74% after 18 months of therapy. In first-episode about 46% continued their initial treatment for 30 days or longer, and 42% discontinued treatment within 1 year.



* Sources:

- Kaplan et al. (2013) . Impact of long-acting injectable antipsychotics on medication adherence and clinical, functional, and economic outcomes of schizophrenia . Dove Medical Press Limited
- Plan SV. (2016) Medication adherence in patients with schizophrenia. Int J Psychiatry Med. 2016; 51 (2): 211-9
- Heres et al (2014). Treatment of early episode in patients with schizophrenia: the role of long acting antipsychotics. European Psychiatry 29 S2 (2014) 1409-1413

LAIs are becoming the goal standard



Most schizophrenia patients (approximately 80% to 90%) experience a relapse during the course of their illness. Breakthrough psychotic episodes may result from nonadherence to maintenance therapy, persistent substance use, poorer premorbid adjustment, or stressful life events. ***Long-acting injectable antipsychotics are commonly used to prevent relapse*.***

Schizophrenia is a debilitating chronic disease that requires lifelong medical care and supervision. Even with treatment, the majority of patients relapse within 5 years, and suicide may occur in up to 10% of patients. Poor adherence to oral antipsychotics is the most common cause of relapse. The discontinuation rate for oral antipsychotics in schizophrenia ranges from 26% to 44%, and as many as two-thirds of patients are at least partially non-adherent, resulting in increased risk of hospitalization. (…) Research shows, however, ***significant improvements in adherence with LAIs compared with oral drugs, and this is accompanied by lower rates of discontinuation, relapse, and hospitalization**.***

Long-acting injectable antipsychotics (LAIs) are among the most effective treatments in psychiatry, (….), ***recent research has suggested that they may also provide an effective treatment strategy for patients with early-phase or first-episode disease****. (…) recent database and randomized controlled studies favor the use of LAIs in early-phase schizophrenia patients. (…)* ***This evidence review, discussion, and summary recommendations may help clinicians, patients, families, payers, and other stakeholders to better characterize the role of LAIs in the treatment of schizophrenia***.***

Sources:
* Chris Fellner (2017). New Schizophrenia Treatments Address Unmet Clinical Needs. P&T, vol.42.Nº2.
** Kaplan et al. (2013) . Impact of long-acting injectable antipsychotics on medication adherence and clinical, functional, and economic outcomes of schizophrenia. Dove Medical Press Limited
*** Correll et al. . The use of Long-Acting Injectable Antipsychotics in Schizophrenia: Evaluating the evidence. J Clin Psychiatry 2016; 77 (suppl 3): 1-24

LAIs: Superior outcome value

- LAIs provide a superior new approach to the treatment of schizophrenia aimed to reduce the relapses which provoke the progression of irreversible and cognitive brain damages.

Monthly dose medically supervised takes away the responsibility of remembering from patients and care givers ensuring continuous therapy provision.

Monthly dose medically supervised ensures that patients stay out of hospital and symptoms are under control and permits early identification of non-adherence to the treatment.

Monthly dose medically supervised ensures reduction of hospitalizations rates and reduction of health cost providing a superior outcome value.

ISM® technology

ISM®: Robust technology

- ROVI has developed a sustained-release injectable technology called ISM® (in-situ microparticles) based in two separated syringes containing a) the drug and polymer (solid state), and b) the solvent (liquid state).
- The ISM® technology is protected by patents until 2033.
- Key advantages compared to existing technologies:
  - ✓ Reduces volume in comparison with other long-acting technologies, so there is a reduction in variability and initial impact and the injection is less painful injection and with less resistance.
  - ✓ Combines different mechanisms of drug release: No lag-timen and Reduced Cmax/Cmin fluctuation.
  - ✓ Extemporaneous reconstitution just before the injection by connecting both syringes all in one single process.
  - ✓ Improved stability and no need for cold chain.

Solid

Liquid

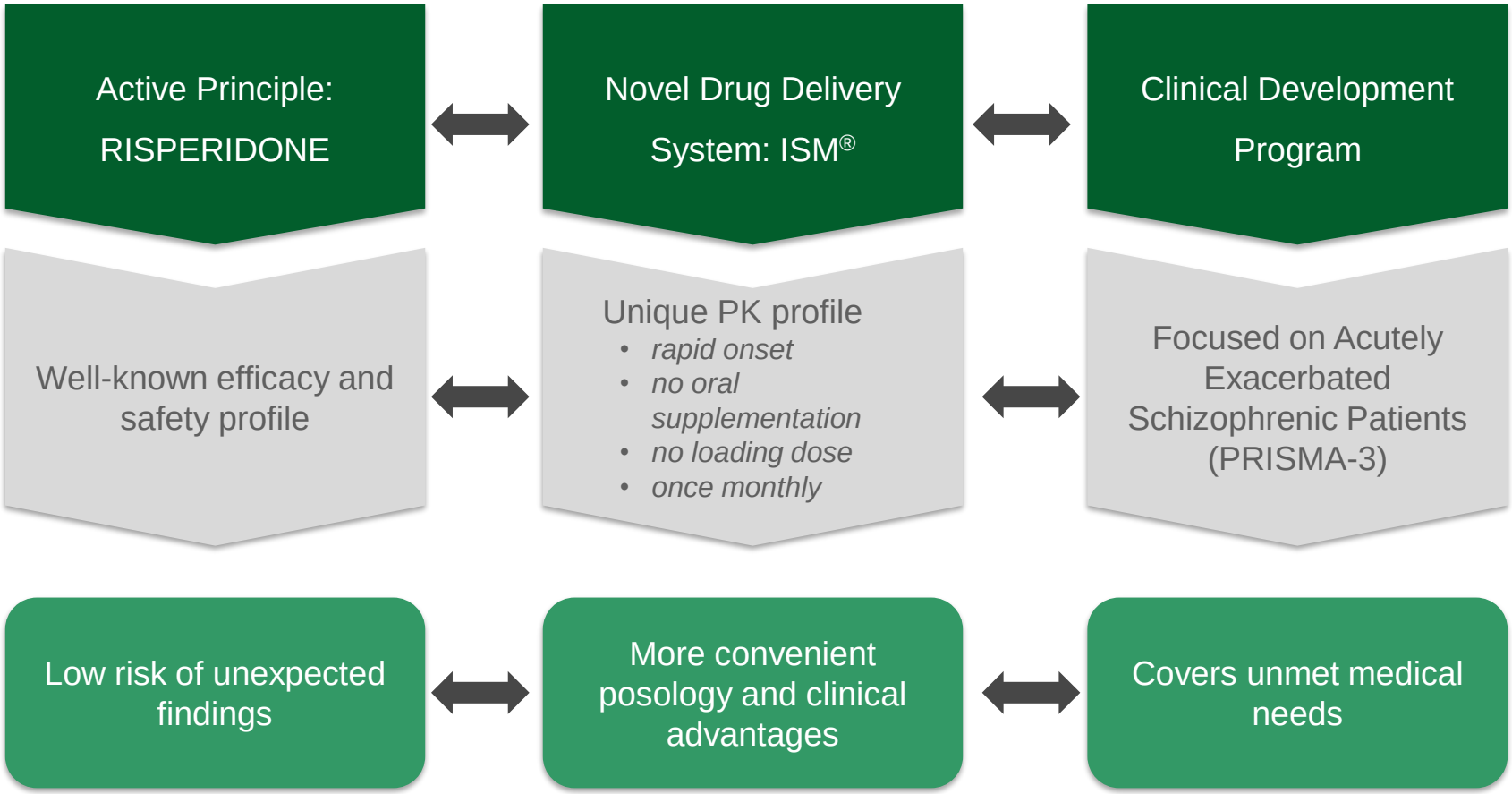
Contains the drug and polymer

Contains the solvent

DORIA®

DORIA®: The fast onset of action long-acting injectable of risperidone

- DORIA® offers ROVI an excellent opportunity to launch an efficiency proven active principle with an innovative system to delivery



Drug development plan of DORIA®

2008 — Non-clinical Studies

2010 — PHASE I
Healthy Volunteers; Single dose; PK; Safety and Tolerability

2013 — agencia española de medicamentos y productos sanitarios
PHASE I (PRISMA-1)
Patients with schizophrenia, Single dose; PK; Safety and Tolerability

2014 — FDA U.S. Food and Drug Administration

2015 — PHASE II (PRISMA-2)
Patients with Schizophrenia
Multiple dose gluteus/deltoids; PK; Safety and Tolerability; efficacy exploratory

2016 — FDA U.S. Food and Drug Administration; EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH

2017-19
- *Ongoing*: PHASE III (PRISMA-3) Acute Exacerbation (12 weeks + 1 year FU); efficacy; safety and tolerability; vs Placebo
- *Planned*: Comparative Bioavailability vs oral Risperdal

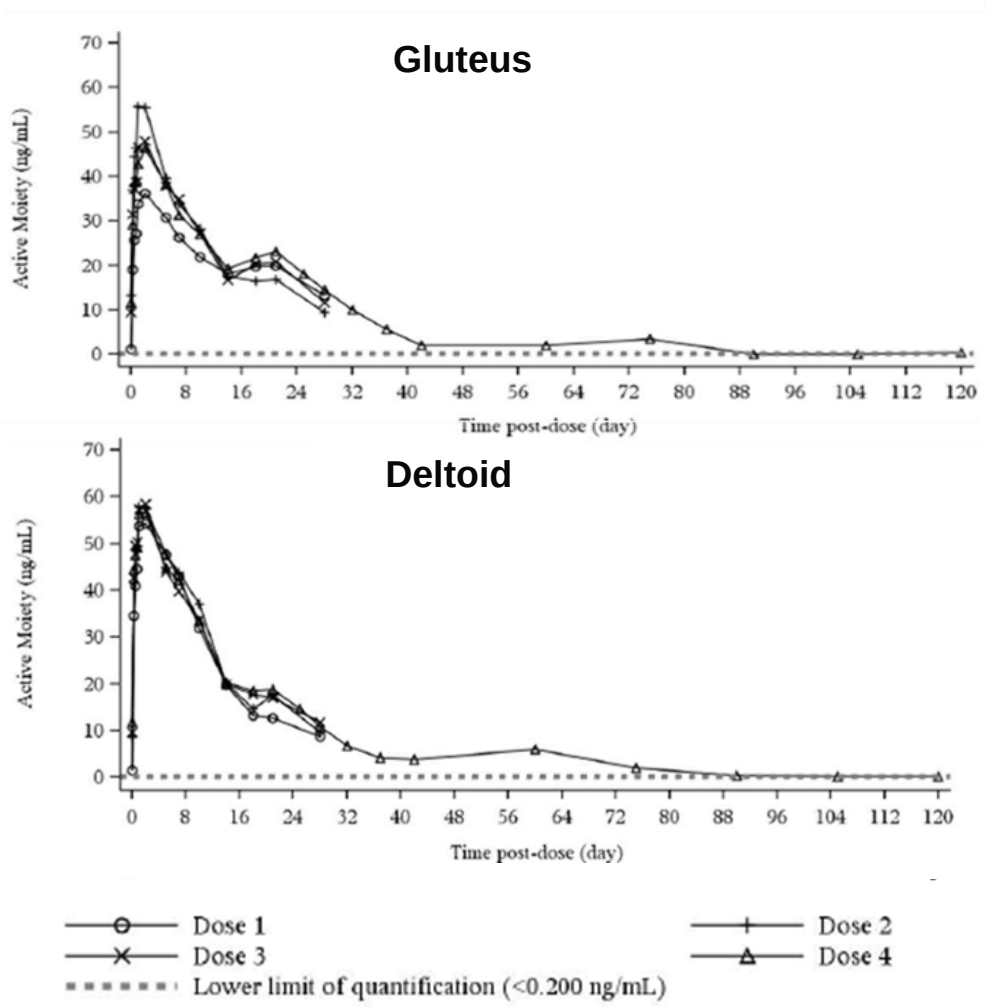
2019-20
- New Drug Application (NDA)
  Marketing Authorization Application (MAA)
- *Potential alternative*: Phase III (PRISMA-4)
  Maintenance efficacy study

Chronic Toxicology

Manufacturing development process

PK pop / Modeling & Simulations

DORIA®: Drug Development Plan (Phase II)



OBJECTIVE:

- Define the PK profile of DORIA® at the steady state
- Evaluate the PK profile after IM administration at gluteal or deltoid muscle

Screening (N=93)
Randomization (N=70)

Deltoid: 75 mg

Gluteus: 75 mg

- DORIA® has therapeutic levels from the first hours after first administration.
- DORIA® provide a sustained release throughout the 4-weeks dosing period over multiple IM injections., independently of the injection site.
- DORIA® is safe and well tolerated

Reference:
Anta L, et al. A Phase II Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of Risperidone ISM® Multiple Intramuscular Injections Once Every 4 Weeks, in Patients with Schizophrenia. Int Clin Psychopharmacol. 2017 (accepted)

DORIA®: Drug Development Plan

Conclusions Phase I & Phase II

01 Therapeutic levels from the first hours after first administration

02 No oral supplementation is required

03 No loading dose is need

04 Suitable for a 4-weekly IM injection (gluteus or deltoids)

05 Similar safety profile as to Risperdal/Risperdal Consta®

06 Modeling and simulations support for pivotal Phase III trial:

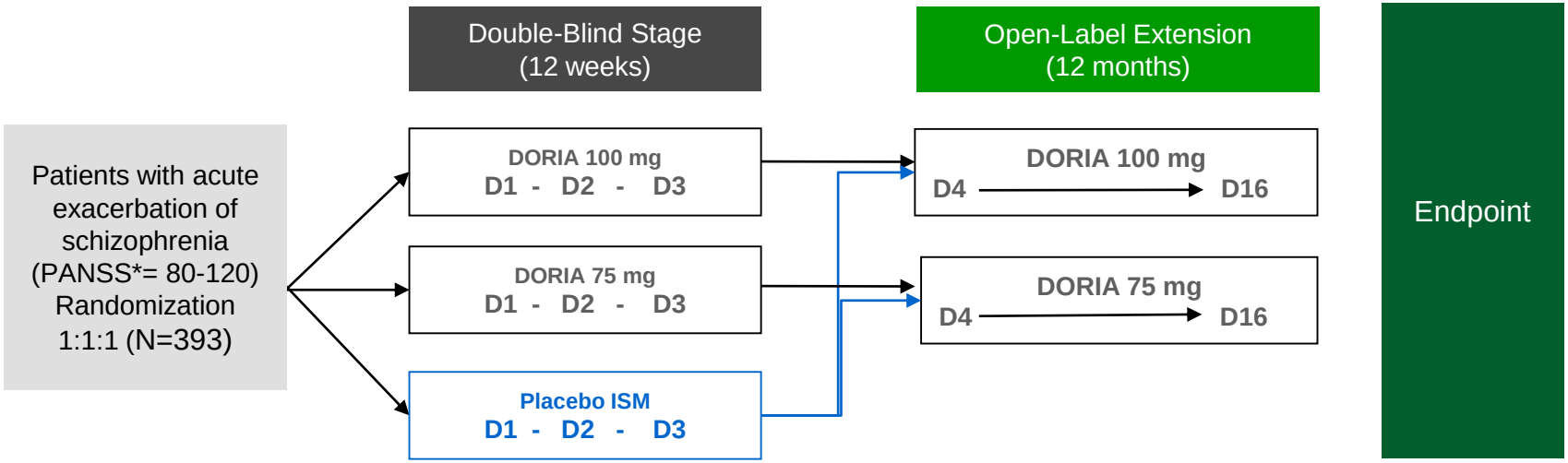
- Dosage selection: 75 mg and 100 mg
- Target population: acutely exacerbated schizophrenia

DORIA®: PRISMA-3 study. Phase III

- Phase III, PRISMA 3, is recruiting since May 2017
- It is double-blind (+open–label extension), parallel, multicentre (31 sites/ 2 countries).

The objectives of Phase III are:

- Evaluate the efficacy and safety of DORIA® as compared with that of placebo in the treatment of subjects with acute exacerbation of schizophrenia.
- Health Resources Utilization (HRU), Health-Related Quality of Life (HRQL), and Social Functioning in subjects treated with DORIA® versus placebo for an acute exacerbation of schizophrenia.
- Explore pharmacokinetic characteristics of DORIA and associations with efficacy.



* PANSS: Positive and Negative Syndrome Scale is a medical scale used for measuring symptom severity of patients with schizophrenia. It is widely used in the study of antipsychotic therapy.

DORIA® - PRISMA-3 study: Efficacy variables

- Endpoint: Study day 85 or the last post-baseline double-blind assessment

Primary efficacy variable

- **PANSS* total score mean change from baseline to endpoint**

Secondary efficacy variable

- CGI-S** score mean change from baseline to endpoint

Other secondary efficacy variable

- Improve CGI-I score mean at endpoint.
- Overall response rate at endpoint.
- PANSS response rate at endpoint (≥ 30% decrease from baseline).
- Time to reach PANSS response.
- PANSS total score mean change from baseline at each post-baseline assessment time point.
- PANSS subscale score mean change from baseline at endpoint and at each post-baseline assessment time point
- For each of the positive, negative, and general psychopathology subscales.
- Overall response rate at each post-baseline assessment time point.
- Time to reach overall response.
- PANSS response rate at each post-baseline assessment time point.
- CGI-S score mean change from baseline at each post-baseline assessment time point.
- CGI-I score mean at each post-baseline assessment time point.

*PANSS: Positive and Negative Syndrome Scale is a medical scale used for measuring symptom severity of patients with schizophrenia. It is widely used in the study of antipsychotic therapy.
**CGI: Clinical Global Impression are mesures of illness severity (CGIS), global improvement or change (CGIC) and therapeutic response.

DORIA® - PRISMA-3 study: HEOR variables

Health Resource Utilization (HRU) and cost variables

- Resources used within and outside the participating center
- By-resource use category (e.g., inpatient services, outpatient services) and total direct medical costs:
  - Time to discharge and hospitalizations,
  - Outpatient/ambulatory visits
  - Health care professional contacts
  - Medication and therapies
  - Community-based day services, primary and community care contacts
- Indirect costs (days absent from work due to illness: measure of lost productivity)
- Assessment for centre vs. patient HRU data collection
- Analyses by country will be considered in light of potential country clustering due to differences in disease management patterns. Country will be included as a co-variable in the regression analysis when testing for differences in the rate of resource use.

Personal and Social Performance Scale (PSP)

- PSP is one of the most commonly used instrument to measure global/social functioning in acute schizophrenia so that indirect comparisons may be made.
- Measure social functioning in four domains:
  - socially useful activities, including work and study
  - personal and social relationships
  - self-care
  - disturbing and aggressive behaviors

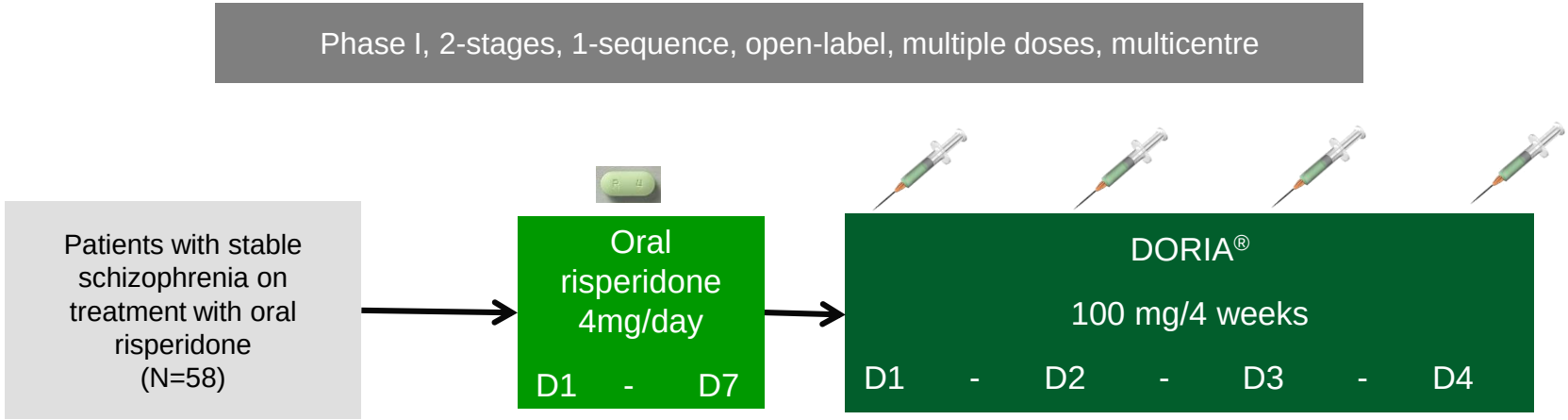
20-item Subjective Well-Being Under Neuroleptics Treatment Scale (SWN-20) disease

- Specific instrument to measure:
  - mental functioning,
  - self-control,
  - emotional regulation,
  - physical functioning, and
  - social integration

DORIA®: Comparative bioavailability

Objectives:

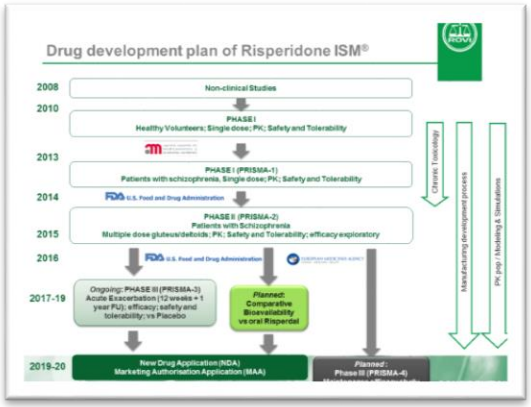
- Assess the comparative bioavailability at the steady state of DORIA® versus oral risperidone in patients with schizophrenia.
- Supportive bridge from oral risperidone data.



DORIA®: Regulatory Strategy

U.S. Food and Drug Administration

- Pre-IND meeting
- End of Phase II meeting
- Special Protocol Assessment



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

- Scientific Advice

NDA under 505(b)(2) Section of FD&C Act

Treatment of Schizophrenia

Hybrid Application
[Article 10(3) - Directive 2001/83/EC]

Treatment of Acute Exacerbation of Schizophrenia

IND: Investigational New Drug
NDA: New Drug Application

DORIA®: Innovation for unmet medical needs in Schizophrenia

	RISPERDAL CONSTA® (Risperidone)	INVEGA SUSTENNA® / XEPLION® (Paliperidone)	INVEGA TRINZA® / TREVICTA® (Paliperidone)	ABILIFY MAINTENA® (Aripiprazole)	ARISTADA® (Aripiprazole Lauroxil)	RBP-7000 (Risperidone Atrigel®) [4]	DORIA® [4] (Risperidone)
Acute Treatment	✗	✓	✗	✗	✓	✓	✓
Once Monthly Administration	✗	✓	✓✓ [3]	✓	✓	✓	✓
No Oral Supplementation	✗	✓	✓	✗	✗	✓	✓
Therapeutic Levels[1] within First 8 h	✗	✗	✗	✗	✗	✓	✓
Intramuscular Injection	✓	✓	✓	✓	✓	✓✓ [5]	✓
Deltoids & Gluteal administration	✓	✓	✓	✓	✓	✗	✓
PANSS[2] reduction from day 4	✗	✗	✗	✗	✗	✗	✓ [6]

Sources: Gefvert O, et al. Int J Neuropsychopharmacol 2005;8(1):27-36. Odou P, et al. Clin Drug Invest 2000;19(4):283-92. Nyberg S, et al. Am J Psychiatry 1999;156(6):869-75).

(1) The therapeutic concentration range of risperidone is quite wide and can vary from 10 ng/mL to 80 ng/mL or even higher

(2) PANSS: positive and negative syndrome scale. Scale used to evaluate the symptoms of patients with schizophrenia

(3) Quarterly administered

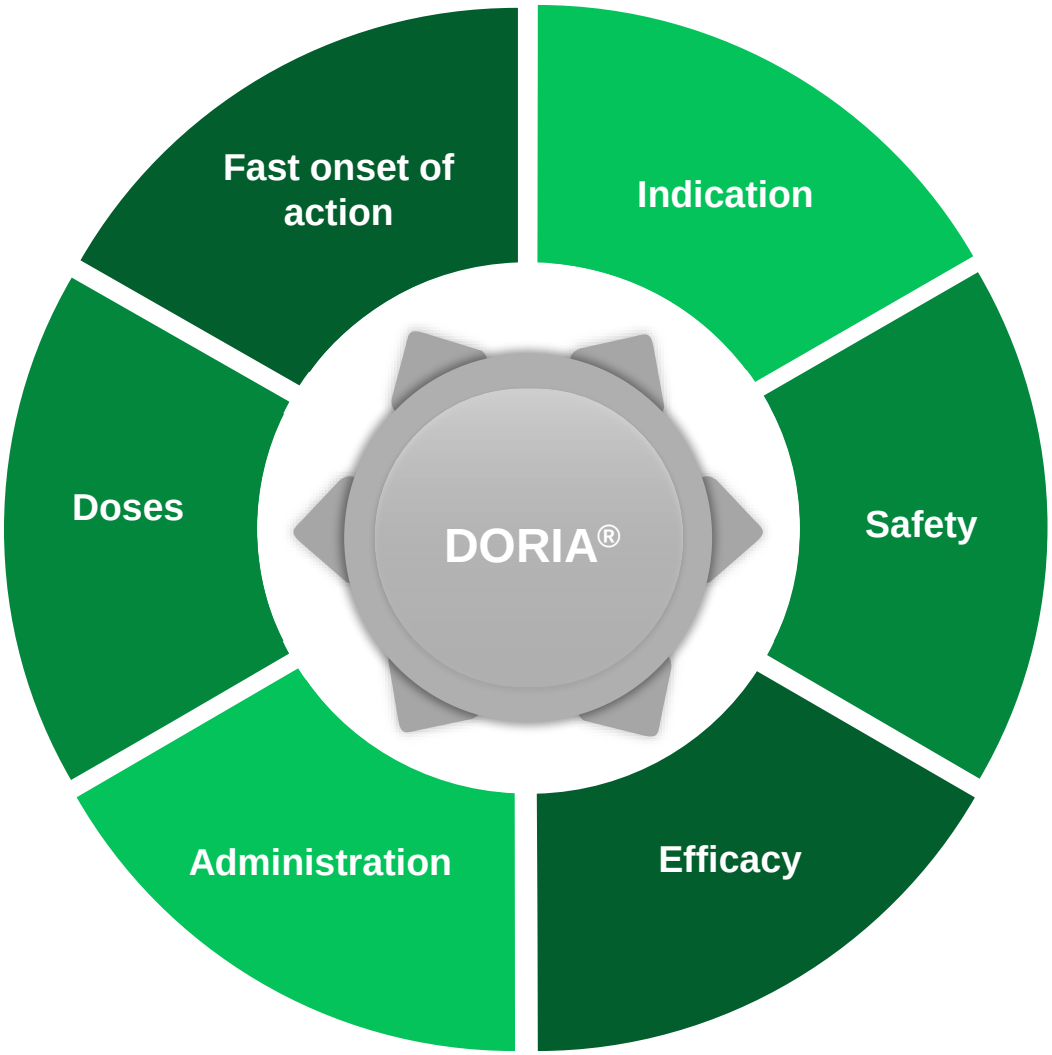
(4) Not marketed yet

(5) Subcutaneous

(6) To be confirmed in the currently ongoing phase III trial PRISMA-3 (ClinicalTrials.gov Id. #NCT03160521)

DORIA®: Predictable and solid clinical outcome

Rapid achievement of therapeutic levels (8h).
No oral supplementation



Treatment of acute exacerbation of schizophrenia

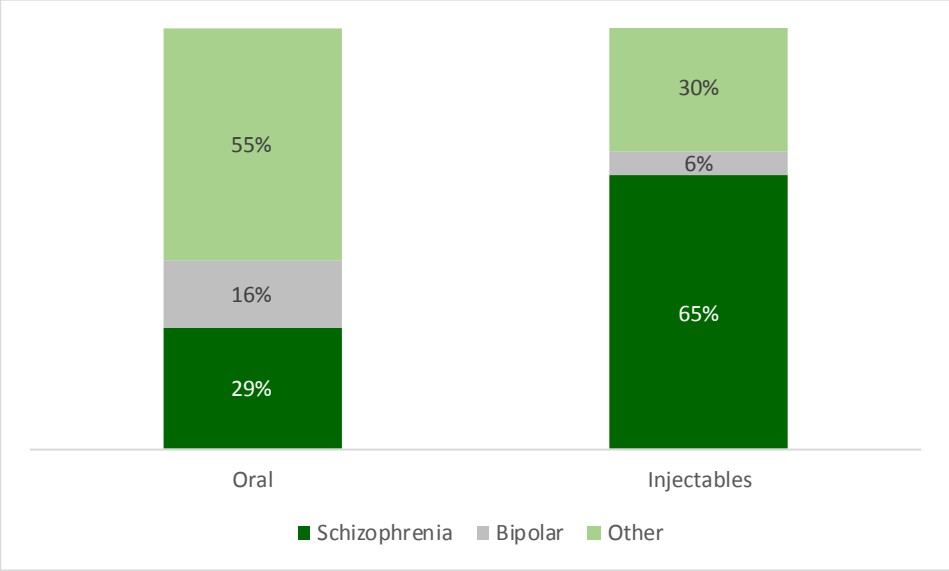
4-weekly administration of risperidone as an IM (gluteus or deltoid) injection.
75 and 100 mg.

Good tolerability. Efficacy in patients experiencing acute exacerbation of schizophrenia. Change in PANSS score.

US and Top-5 European Schizophrenia Markets

IMS data and Kantar Health

- ROVI primarily needed to assess the commercial potential of DORIA® and gain a better understanding of the schizophrenia market trends over the long term in order to prepare the future commercialization of the product.
- The market research objective is to identify the market potential of DORIA® as well as the probable market scenarios that ROVI may face when launching the product.
- For those purposes, ROVI has contracted "IMS Midas" and the Consultancy "Kantar Health" a Forecast model in US and Top-5 Europe.
- The market focus in the forecast is comprised of schizophrenia in order to avoid overstating the size of the market.

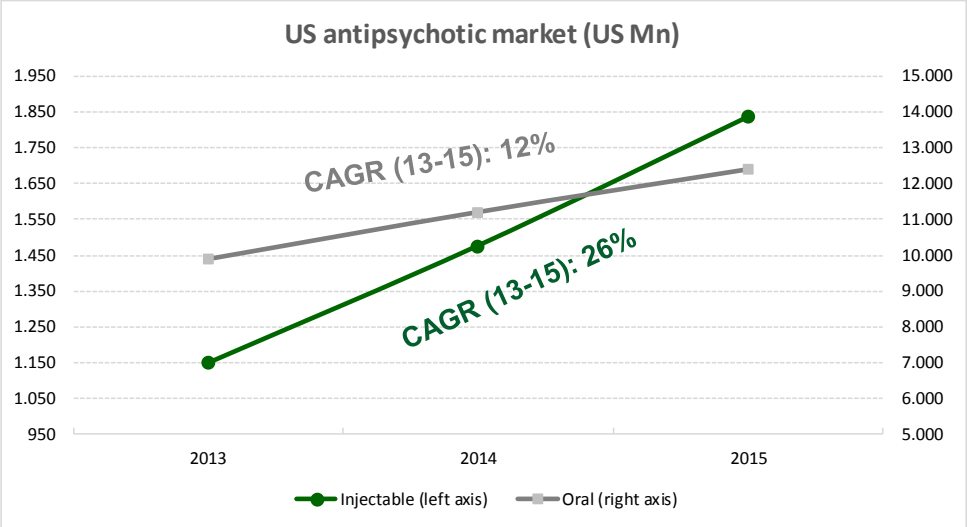


- 65% of injectable antipsychotic market (in units) are to treat schizophrenia*.
- In oral treatments this percentage decreases to 29%.

* Source: IMS Midas

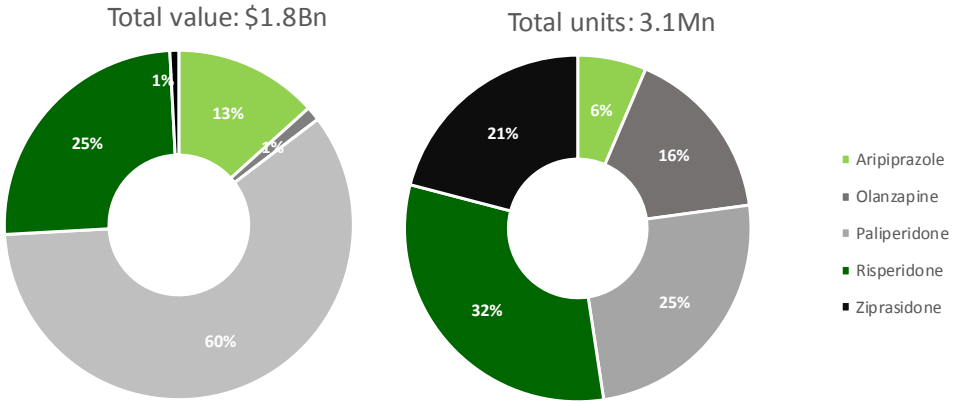
Antipsychotics market in US*

- US is the largest antipsychotics market* worldwide with 2015** sales of **$14.2Bn**.
- In terms of value, oral represents 87% and injectable 13% of total antipsychotic sales in 2015**.
- Injectable market increased 26% CAGR (2013-2015)*** while oral increased 12% CAGR same period.



US antipsychotic injectable market by molecule (2015**)

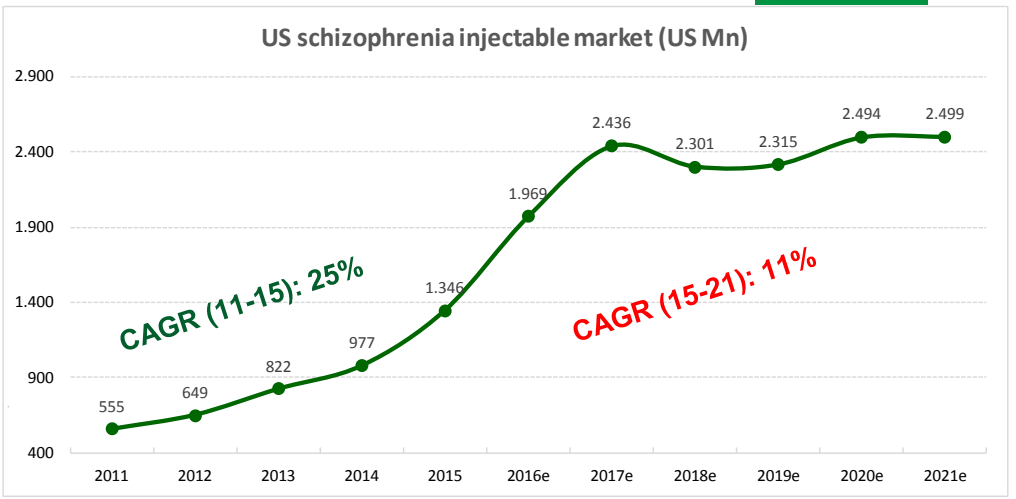
- Most important molecule in value is paliperidone with 60% market share, followed by risperidone with 25% market share.
- In units, most important molecule is risperidone, with 32% market share, followed by paliperidone with 25% market share.

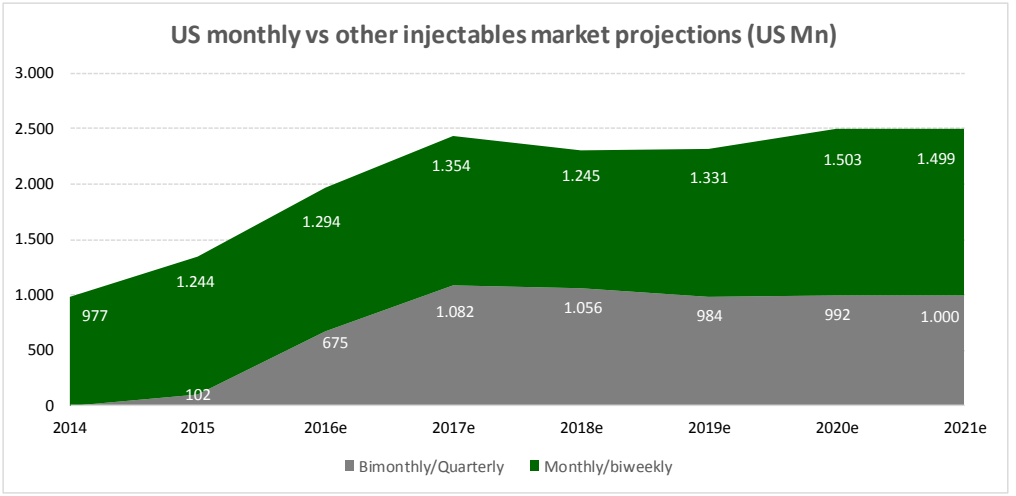


* Source: IMS Midas
** Annual period from Q3 2014-Q2 2015
*** Periods: Q3 2012-Q2 2013; Q3 2013-Q2 2014; Q3 2014-Q2 2015

Schizophrenia injectable market in US*

- US is the largest schizophrenia injectable market worldwide with annual sales in 2015 of **$1.3Bn** and **1.4Mn units**.
- The market has grown +25% CAGR (2011-2015) in value and +7% CAGR (2011-2015) in units.
- In 2021, the market is expected to reach $2.5Bn in value, +11% CAGR (2015-2021), and 2.8Mn units, +12% CAGR (2015-2021).
- Monthly/biweekly medication market is expected to have 60% market share in value in 2021 with $1.4Bn, against bimonthly/ quarterly medication.
- Average yearly treatment** in 2015 is $10,764 for monthly/biweekly treatments.

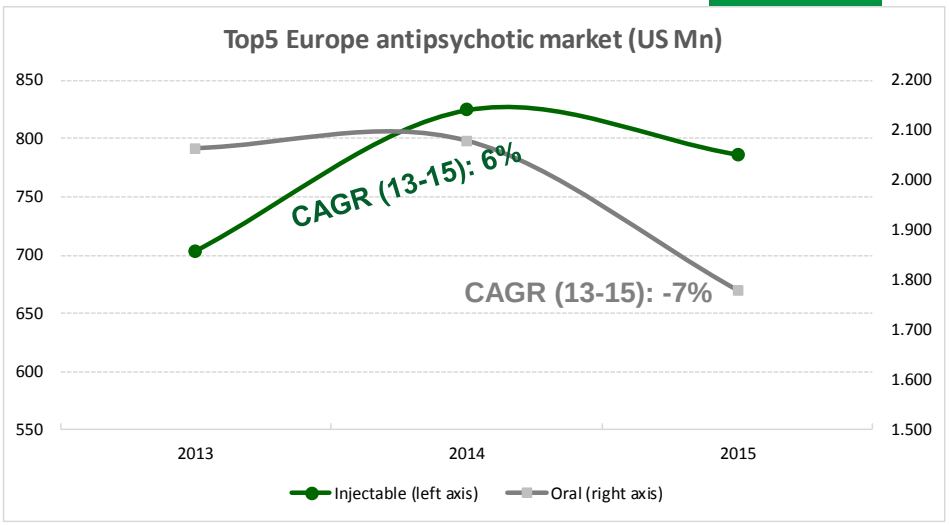




* Source: IMS Midas July 2015
** Average yearly treatment price for monthly and biweekly, bimonthly and quarterly treatments

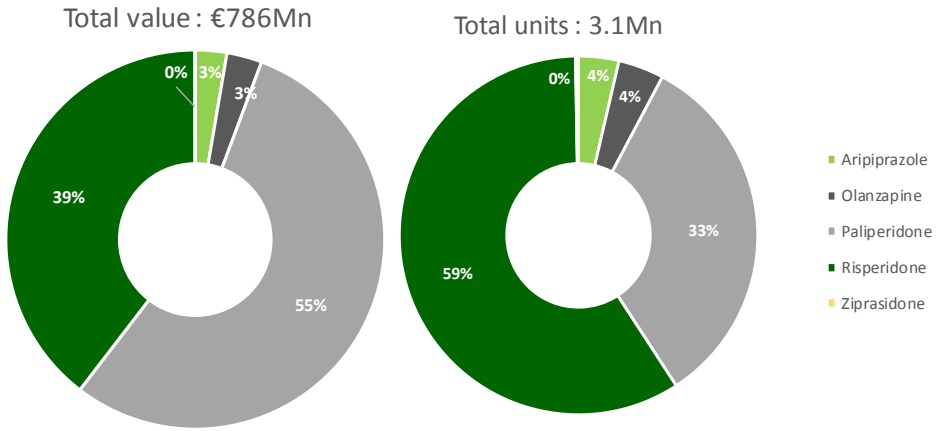
Antipsychotics market in Top-5 Europe*

- Top5 largest markets in Europe are France, Germany, Italy, Spain and UK.
- Top5 market is one of the top antipsychotics market worldwide with 2015** sales of with **$2.6Bn**.
- In terms of value, oral represents 69% and injectable 31% of total antipsychotic sales in 2015**.
- Injectable market increased 6% CAGR (2013-2015)*** while oral decreased -7%



Top-5 Europe antipsychotic injectable market by molecule (2015)**

- Most important molecule in value is paliperidone with 55% market share, followed by risperidone with 39% market share.
- In units, most important molecule is risperidone, with 59% market share, followed by paliperidone with 33% market share.



* Source: IMS Midas
** Annual period from Q3 2014-Q2 2015
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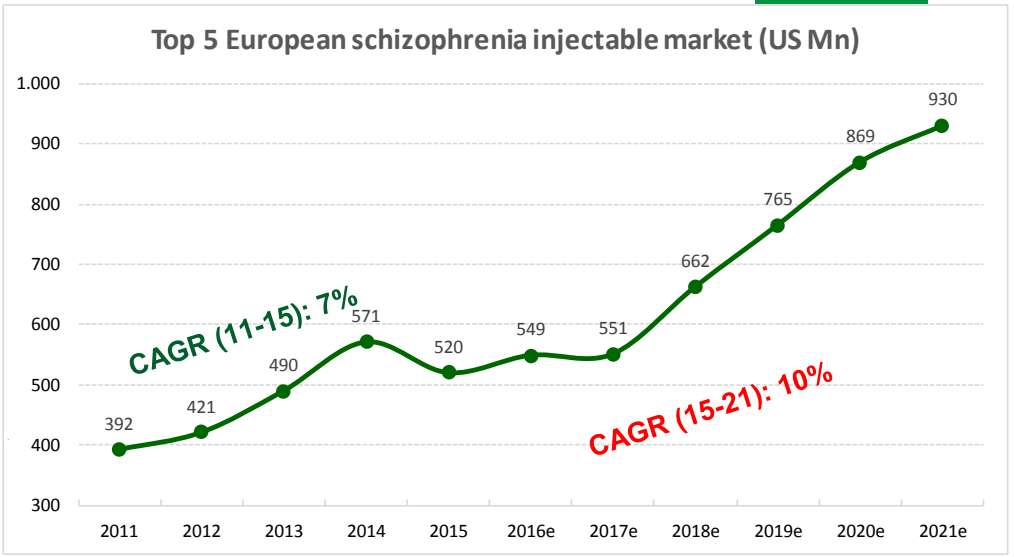
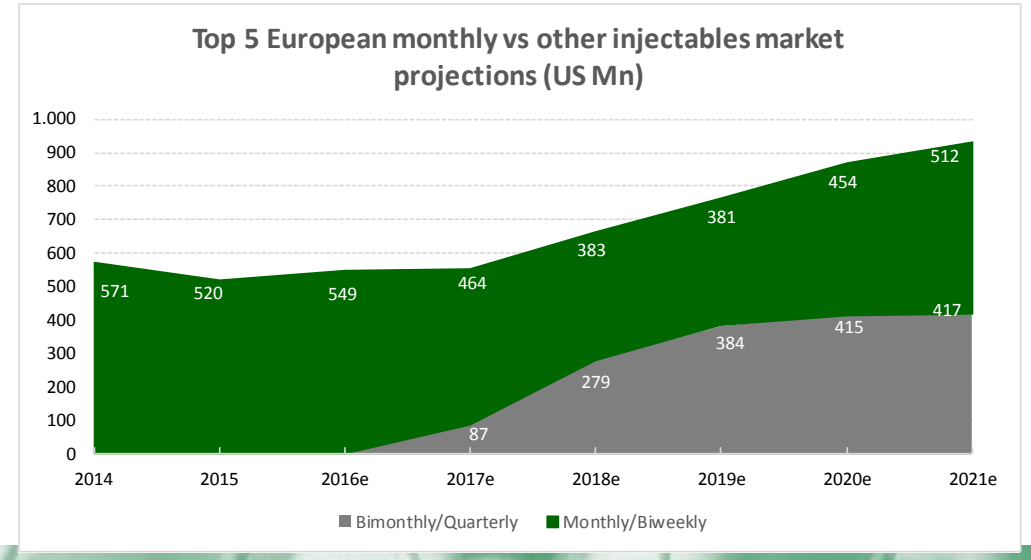
Schizophrenia injectable market in Top5 Europe*

- Top 5 Europe has a schizophrenia injectable market sales of **$520Mn** and **2.1Mn units** in 2015.
- The market has grown +7% CAGR (2011-2015) in value and +4% CAGR (2011-2015) in units.
- In 2021, the market is expected to reach $930Mn in value, +10% CAGR (2015-2021), and 3.6Mn units, +10% CAGR (2015-2021).
- Monthly/biweekly medication market is expected to have 55% market share in value in 2021 with $513Mn, against bimonthly/ quarterly medication.
- Average yearly treatment** in 2015 is $3,650 for monthly/biweekly treatments.





* Source: IMS Midas July 2015

** Average yearly treatment price for monthly and biweekly, bimonthly and quarterly treatments

DORIA®: ROVI's strategy

- The strategy of the Company related to DORIA® is aliened

R&D team fully dedicated	Owner of technology	Manufacturing Plants	Limited Sales Force
• ISM® projects have a dedicated team of around 50 people.	• The ISM® technology belongs to ROVI.	• GMD & FDA plants. • Quality proved so reduces risks for the future approvals. • Capex investment already done in ISM® plants, built and running. • Fully integrated plants.	• DORIA® requires a small sales force because medical targets are psychiatrists in acute medical setting (4,034 psychiatrists hospital based in US).
We invest in good professionals	Key issue compared to competitors	Low risk of delays in regulatory process	Perfect fit with ROVI's specialty pharma strategy.

DORIA® is expected to have good margins, as manufacturing process will be fully integrated and LAIs prices are high.

Update on Enoxaparin and Letrozol ISM®

Enoxaparin business

- In September, ROVI announced the commence of the enoxaparin marketing in Germany.
- ROVI is following a double strategy in distributing the biosimilar of enoxaparin, based on:

A	**Direct presence in some countries through local subsidiaries**	• Local offices have been registered in Top 5 European countries. • ROVI will have its own sales force in selected countries.	✓ Rovi GmbH: Germany ✓ Rovi Biotech Limited: UK ✓ Rovi Biotech S.R.L.: Italy ✓ Rovi SAS: France
B	**Partnership with domestic and/or international players**	✓ Distribution through domestic and/or international players. ✓ Potential agreements based on up-front fees, royalties and milestones.	✓Outside US and Europe, distribution agreements (subject to marketing authorization to be granted by local authorities in each country).

- ROVI has the national registration approval in Germany, France, UK, Hungary, Slovenia, Estonia Latvia and Slovakia.
- The Company has limited initial capacity subject to regulatory variations for the first 18/20 months, so the contribution of these subsidiaries to sales will depend on German demand.
- Projections of enoxaparin biosimilar cost are expected to be around €8Mn for 2018, related to marketing expenses.

Letrozole ISM®: LISA-1 study

- Letrozole is the key treatment for breast cancer hormone receptor+

Breast cancer

- The annual incidence of breast cancer in Europe is 110/100,000 and it is the main cause of cancer related death in European women
- Tumors with incomplete expression or high level of oestrogen and/or progesterone receptors are considered endocrine responsive

Aromatase Inhibitors

- Aromatase inhibitors (AI), letrozole, anastrozole and exemestane, block the production of oestrogen in postmenopausal women
- Postmenopausal women must be considered to receive AI for a maximum of 5 years, either as primary therapy or after 2-3 years of tamoxifen
- AIs are more effective than tamoxifen in postmenopausal women with hormone responsive breast cancer
- Current posology of AIs: once daily orally
- Evidence suggests long-term hormone therapy (HT) adherence, for breast cancer, may represent an area limiting optimal breast cancer patient treatment
- Early discontinuation and non-adherence to HT are common and associated with increased mortality

Sources:
- ESMO Guidelines Working Group. Ann Oncol 2009
- ASCO Clinical practice guideline. J Clin Oncol 2010
- Chlebowski RT, Geller ML. Adherence to endocrine therapy for breast cancer. Oncology. 2006;71(1-2):1-9.
- Hershman DL, et al. Early discontinuation and non-adherence to adjuvant hormonal therapy are associated with increased mortality in women with breast cancer. Breast Cancer Res Treat. 2011;126(2):529-37.

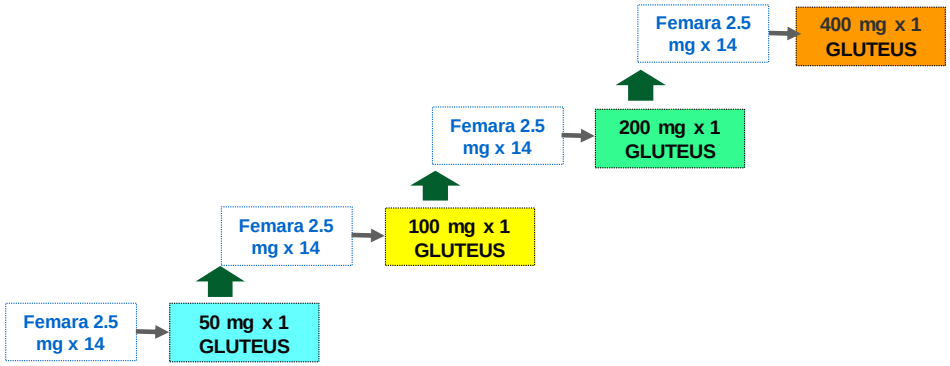
Letrozole ISM®: LISA-1 study

- The objective is to obtaining a long-term injectable formulation of letrozole and its inclusion in the market for maintenance treatment in breast cancer in post-menopausal HR + women.
- Potential advantages are:
  - First injectable depot of an aromatase inhibitor
  - Improved patient quality (decrease dose frequency, psychological impact of daily memory of illness)
  - Decreased health care costs
  - Improved therapeutic compliance = improved clinical variables (to be proved)

Design of Phase I: LISA-1

Phase I, Open-label, Single Dose Escalation

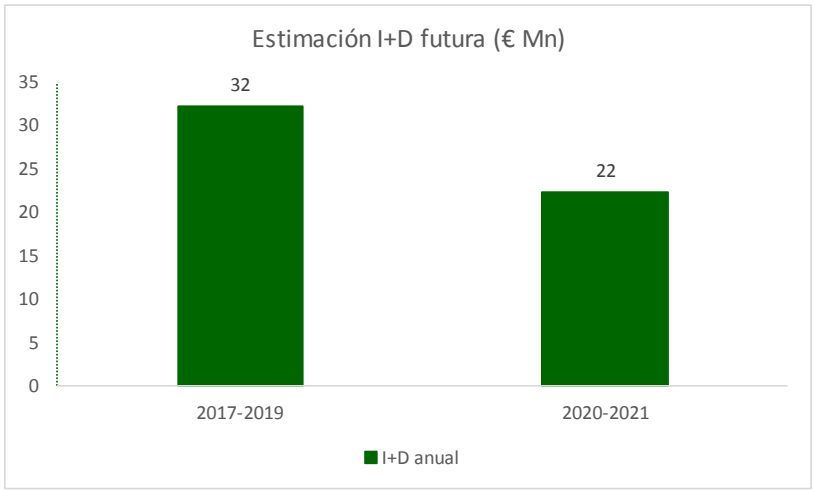
- The objective is to define the pharmacokinetic and pharmacodynamic profile of Letrozole ISM® at different single dose levels in healthy postmenopausal women.

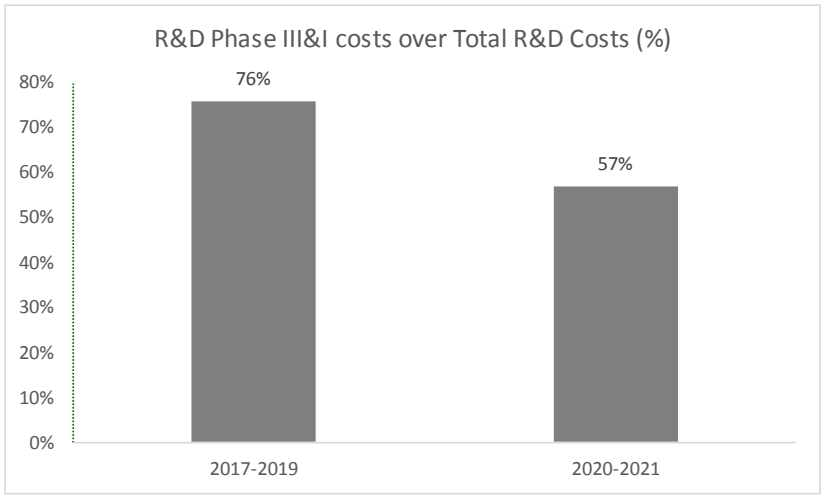


Projections of R&D costs

Projections of R&D costs*

- ROVI will need an important R&D investment for the coming years, to develop DORIA® Phase III together with Letrozole ISM® Phase I.
- This cost will be the pillars for future growth.
- In the period 2017-2019, the average cost of R&D will be around €32Mn per year.
  - ➢ 76% of those R&D costs would represent Phase III of DORIA® and Phase I of Letrozole.
- In the period 2020-2021, this average decreases to €22Mn per year.
  - ➢ 57% of those R&D costs would represent Phase III of DORIA® and Phase I of Letrozole.





* Source: ROVI estimates

Conclusions

Conclusions

- ROVI is going through a transformational moment launching our biosimilar of enoxaparin in Europe and the evolution of our R&D pipeline.
- In-house products will be an important % of total sales in the coming years and international presence will increase significantly and will make ROVI a international company with high value added portfolio.
- This R&D is one of the main pillars for future growth, and it is very important for the Company in the coming years.
- The cost of R&D will be finance by traditional pharma business and enoxaparin biosimilar sales, last product launched in Europe to spread internationally ROVI's fingertip.
- ISM® Technology brings the possibility of competing in new therapeutic areas, such as psychiatry and oncology:
    - DORIA® is in Phase III stage, focused in schizophrenia patients.
    - Letrozole ISM® is in Phase I stage, focused in breast cancer patients.
- Investing in the field of prolonged drug release using ISM® technology opens up the possibility of competing in new markets, as long-acting injectable business is growing worldwide as compliance rates improve with these products.
- We will continue our sustained growth investing in technology and searching new niche products for our ISM® platform.

DORIA®: An optimal profile for a LAI

Monthly injection for a fully medical supervision in the medical setting:

Providing a mechanism for monitoring adherence with injections

Regular interactions between patient and medical staff

Medical target: Psychiatrist in acute medical setting

Small sales force size

Reduced relapse frequency and re-hospitalization rates

Clear attribution of the cause of relapse or non-response, discriminating between non adherence or lack of response

Antipsychotic drug with well known for each efficacy such as risperidone

Election of choice for acute episodes

Fast onset of action to achieve therapeutic plasma levels from the beginning

No need oral supplementation

Reducing hospitalization time