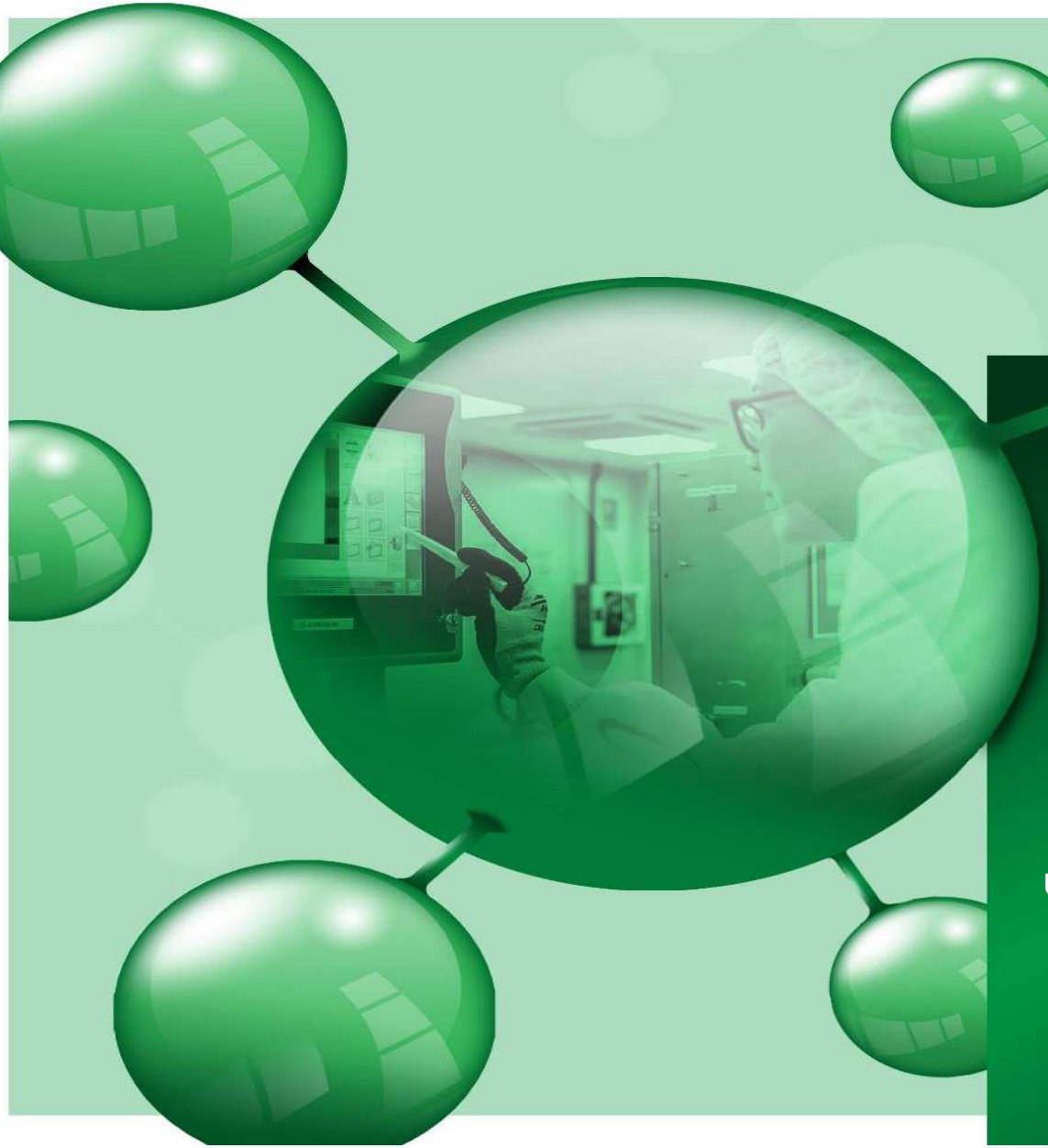

Update on Doria® regulatory processes

MARCH 2021

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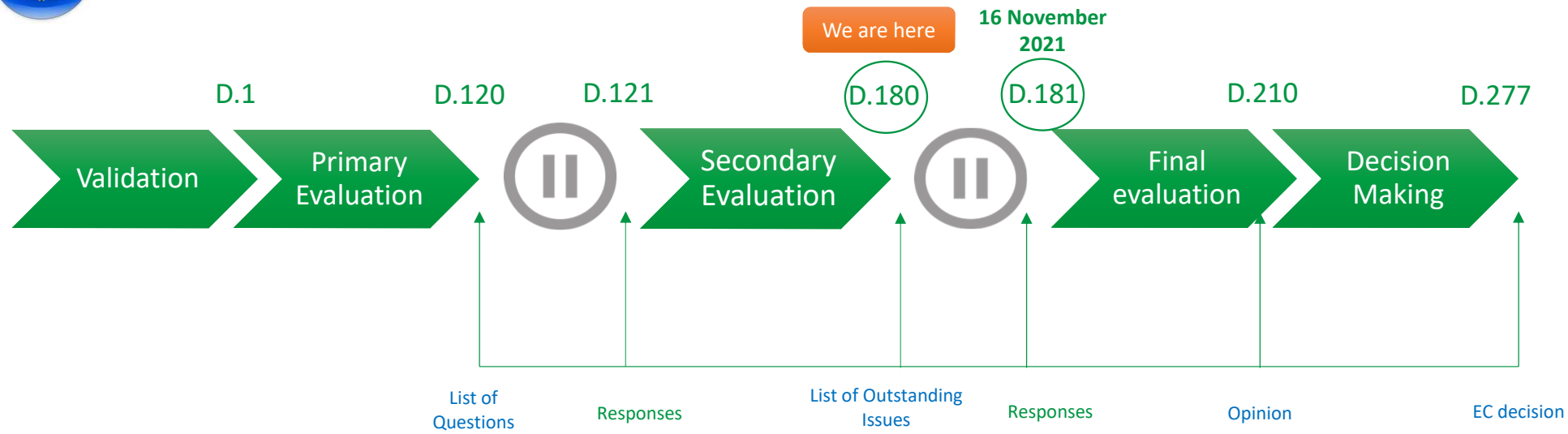
European regulatory process – Where we are?



ROVI requests a clock-stop to answer a major objection: Repeat BORIS[1] study with European reference product

- ✓ Objective: repetition of BORIS[1] study using Risperdal®[2] marketed in EU
- ✓ BORIS[1] study is a clinical trial which compares the pharmacokinetics of Doria ® vs oral risperidone medicine, Risperdal®. Risperdal®[2] marketed in USA was used in the BORIS[1] study.
- ✓ ROVI expected the trial using Risperdal®[2] marketed in USA to be valid for Europe as Risperdal®[2] marketed in USA and Risperdal®[2] marketed in EU can be considered bioequivalents based on the in vitro and in vivo studies conducted by ROVI
- ✓ A second major objection was received to avoid issues related to the potential lack of flexibility when starting with a long-acting formulation. It is expected to be solved with proposed changes in Product Information.
- ✓ Other non-major concerns pending to be answered in D181.

Limited clinical risk

Cost of around €6Mn

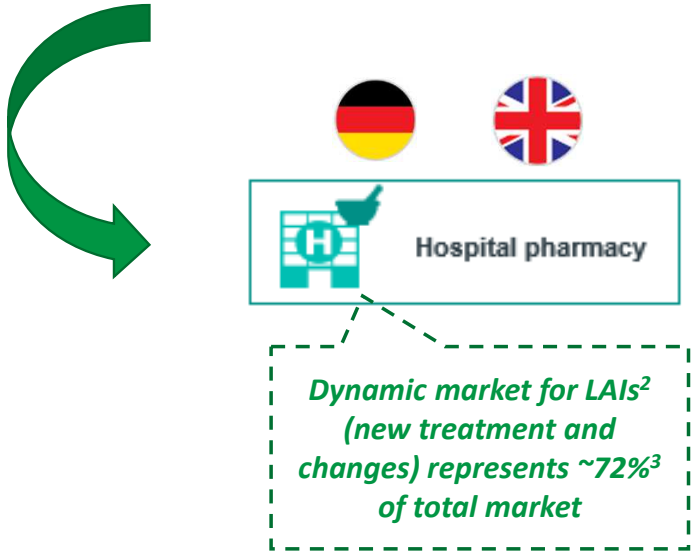
Clock-stop for D181 response granted by CHMP[3]: New information to be provided in November 2021

1. https://clinicaltrials.gov/ct2/show/NCT03527186
2. Trademark registered by Johnson and Johnson
3. Committee for Medicinal Products for Human Use

Therapeutic Indication – Covering the Unmet Medical Need (1/2)

Requested Therapeutic Indication to EMA → **Treatment of Schizophrenia in adults**

Doria® would be the **ONLY[1] Long-Acting Injectable Antipsychotic** that can be administered to **unstable patients** with severe or moderate psychotic symptoms suffering a relapse



- ✓ Dynamic market originating in hospitals
- ✓ In Germany and UK, around 72% of prescriptions in hospitals correspond to patients who start treatment with a LAI[2]
- ✓ Competitive advantage because of the potential unique indication of Doria®

[1] In the European Union
[2] LAI: Long-Acting Injectable
3 Source: IQVIA

Therapeutic Indication – Covering the Unmet Medical Need (2/2)

Doria® has a **unique Pharmacokinetic profile** making the product suitable to treat stable schizophrenia patients as well as unstable schizophrenia patients requiring a fast onset of action

ACHIEVES FAST THERAPEUTIC PLASMA LEVELS[2,3]

NO LOADING DOSE/ORAL SUPPLEMENTATION NEEDED[1-3]

SUSTAINED THERAPEUTIC LEVELS ALLOWING A ONCE MONTHLY POSOLOGY[1-3]

PRISMA-3: DORIA® DEMONSTRATED EFFICACY IN SEVERE PATIENTS AS EARLY AS DAY 8[1]

1. Correll CU, et al. Efficacy and safety of once-monthly Risperidone ISM® in schizophrenic patients with an acute exacerbation. NPJ Schizophr. 2020 Nov 25;6(1):37
2. Anta L, Llaudó J, Ayani I, Martínez J, Litman RE, Gutierro I. 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. 2018 Mar;33(2):79-87.
3. Llaudó J, Anta L, Ayani I, Martínez J, Schronen J, Morozova M, Ivanov M, Gutierro I. Phase I, open-label, randomized, parallel study to evaluate the pharmacokinetics, safety, and tolerability of one intramuscular injection of risperidone ISM at different dose strengths in patients with schizophrenia or schizoaffective disorder (PRISMA-1). Int Clin Psychopharmacol. 2016 Nov;31(6):323-31.

USA regulatory process – Where we are?

The recommended follow-up phases with the FDA[1] were covered:

- Pre-IND[2]
- IND[2]
- End of phase II
- Pre-submission meeting

ROVI submitted the dossier to the FDA[1] on November 24, 2020

FDA completed its filing review and determined that ROVI application is sufficiently complete to permit a substantive review. Application[3] considered filed 60 days after the application date

The user fee goal date is September 24, 2021

The indication pursued in the US is the same as all other LAIs[4] have, "Treatment of schizophrenia in adults"

1. FDA: Food and Drugs Administration
2. IND: Investigational New Drug
3. In accordance with 21 CFR 314.101 (a)
4. LAI: Long.-Acting Injectable

Product Launch (subject to obtaining the relevant authorisations)

- ✓ **Due to the COVID-19 pandemic, the launch of the product would probably have been delayed until the market conditions were more favorable**
- ✓ **Doria® expected to be launched in Europe in Q1 2022**
- ✓ **Germany and UK: first markets to enter**
- ✓ **2021 operating revenue guidance (+20%-30%) not impacted by the delay of the Doria® launch**

Commercialization in Europe

Commercialization in USA

Q1 2022E

2022E