

DELTYBA PRESS-RELEASE – FOR IMMEDIATE RELEASE

Otsuka and Ewopharma AG join the fight against tuberculosis in Romania by launching Otsuka’s orphan drug Deltyba® (delamanid) for multidrug-resistant tuberculosis.

SCHAFFHAUSEN, 20th January 2020. Tuberculosis (TB) is the leading cause of death from an infectious disease in the world.¹ Otsuka Pharmaceutical Co., Ltd has developed Deltyba (delamanid), for the treatment of adults with pulmonary multidrug-resistant TB (MDR-TB). MDR-TB is defined as TB that is resistant to the most potent first-line agents (rifampicin and isoniazid) and is one of the most difficult forms of TB to treat with a worldwide treatment success rate of only around 56% (MDR-TB/rifampicin-resistant TB)².

Ewopharma and Otsuka’s subsidiary, Otsuka Novel Products GmbH (ONPG), the European Union marketing authorisation holder for Deltyba, have signed a commercial agreement enabling Ewopharma’s Romanian affiliate to commercialise Deltyba in the country. Mr Cristian Stanciu, Country Manager of Ewopharma Romania says: “We are honoured that Otsuka has chosen to collaborate with us as their local representative in Romania. TB, and in particular, MDR-TB, is a big public health problem in Romania. We are committed to increasing access to new therapeutic options to treat this deadly disease, and by doing so, contribute to eliminating TB in Romania.”

ONPG’s Managing Director, Robert Dornheim adds: “Otsuka is committed to enhancing access to Deltyba and promoting good antimicrobial stewardship through collaborations with committed organisations, such as Ewopharma, who share Otsuka’s mission and vision of fighting back against MDR-TB. Together, we look forward to supporting education on the responsible use of TB medicines and working with reputable centres experienced in the management of MDR-TB treatment and care.”

About Deltyba®

Deltyba is a tuberculosis medicine that contains the active substance delamanid. Tuberculosis is an infection caused by the bacterium *Mycobacterium tuberculosis* (*M. tuberculosis*). Deltyba is indicated for use as part of an appropriate combination regimen for pulmonary multi-drug resistant tuberculosis (MDR-TB) in adult patients when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability³. Because the number of patients with tuberculosis is low in the EU, the disease is considered ‘rare’, and Deltyba was designated an ‘orphan medicine’ (a medicine used in rare diseases) on 1 February 2008. Further information can be found at [EMA](#)⁴.

¹ Executive summary, page 1, WHO 2019 Global TB report <https://apps.who.int/iris/bitstream/handle/10665/329368/9789241565714-eng.pdf?ua=1> (accessed 24/10/2019)

² paragraph 4.3.3, page 102, WHO 2019 Global TB report <https://apps.who.int/iris/bitstream/handle/10665/329368/9789241565714-eng.pdf?ua=1> (accessed 24/10/2019)

³ https://www.ema.europa.eu/en/documents/product-information/deltyba-epar-product-information_en.pdf (July 2019 - accessed 24/10/2019)

⁴ <https://www.ema.europa.eu/en/medicines/human/EPAR/deltyba#product-information-section> (accessed 24/10/2019)

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About Otsuka Novel Products GmbH

Otsuka Novel Products GmbH, based in Munich, Germany, is dedicated to finding innovative solutions to fight the global pandemic of tuberculosis (TB). As the European Union marketing authorization holder for Delyba, ONPG works in collaboration with other Otsuka group companies, partners, non-governmental organisations and other stakeholders, to expand global access to Delyba and fight multidrug-resistant TB.

ONPG is a part of Otsuka Pharmaceutical Company, Ltd., a subsidiary of Otsuka Holdings Co., Ltd. headquartered in Tokyo, Japan. Otsuka Pharmaceutical is a global healthcare company with the corporate philosophy: "Otsuka - people creating new products for better health worldwide."

Otsuka researches, develops, manufactures and markets innovative products, with a focus on pharmaceutical products to meet unmet medical needs and nutraceutical products for the maintenance of everyday health. Further information is available at www.otsuka.co.jp/en/pharmaceutical-business/.

About Ewopharma AG

Ewopharma AG, headquartered in Schaffhausen, Switzerland, is a pharmaceutical marketing company focused on Central Eastern Europe and Switzerland. With nearly 60 years' presence in the region, Ewopharma has extensive knowledge of these markets and enjoys a privileged position in the area. The company covers all aspects of market access and commercialisation of ethical pharmaceutical and consumer health products. Further information is available at www.ewopharma.com

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