

Zydus and Synthron enter into an exclusive licensing and supply agreement for Palbociclib Tablets (generic version of IBRANCE®) for the US market

Ahmedabad, India and Nijmegen, Netherlands, January 18, 2024

Zydus Lifesciences Ltd., a global innovation driven healthcare company announced that its wholly owned subsidiary, Zydus Worldwide DMCC, has entered into an exclusive licensing and supply agreement with Synthron BV for Palbociclib Tablets (a generic version of IBRANCE®) for the US market.

Under the terms of this agreement, Synthron will be responsible for obtaining regulatory approval for Palbociclib Tablets, the generic version of IBRANCE®, and thereafter, for the manufacturing and supply of the product. Zydus will be responsible for commercialization of the product in the US. Synthron was the first sole ANDA applicant for Palbociclib Tablets, 75 mg, 100 mg, and 125 mg, with a paragraph IV certification and therefore may be eligible for 180 days of generic drug exclusivity for all three strengths.

IBRANCE®, is a kinase inhibitor indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with:

- an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or
- fulvestrant in patients with disease progression following endocrine therapy.

Speaking on the development, Managing Director of Zydus Lifesciences Ltd., Dr. Sharvil Patel said, “We are pleased to partner with Synthron for the commercialization of this drug product in the US market. The partnership will bring access to a high unmet need therapy area for patients in the US. We are certain that by pooling our resources and knowledge, we will meet critical needs of patients and stakeholders.”

Anish Mehta, Chief Executive Officer, Synthron BV commented, “As a leading global developer and manufacturer of high quality, complex generics, we are delighted to partner with Zydus on this

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significant first to market opportunity. Bringing Palbociclib tablets to market represents another example of Synthon's global development, manufacturing and regulatory expertise. We are confident that working with Zydus will allow us to successfully commercialize Palbociclib while advancing our mission of enabling access and to high quality, affordable medicines.”

The total addressable market opportunity of Palbociclib Tablets in the US is approximately \$3.1 billion as per the IQVIA MAT Nov. 2023.

About Zydus

Zydus Lifesciences Ltd. with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global life sciences company that discovers, develops, manufactures, and markets a broad range of healthcare therapies. The group has a significant presence in cancer related therapies and offers a wide range of solutions with cytotoxic, supportive & targeted drugs. The group employs over 25,000 people worldwide, including 1,400 scientists engaged in R & D, and is driven by its mission to unlock new possibilities in life sciences through quality healthcare solutions that impact lives. The group aspires to transform lives through path-breaking discoveries. For more details visit www.zyduslife.com

About Synthon

Synthon is a leading pharmaceutical company specializing in the development, manufacturing and commercialization of high quality, complex generic pharmaceuticals globally. For more than 3 decades, Synthon’s more than 1,600 dedicated employees have brought over 100 generic molecules to over 100 markets around the world. As a global leader in generic medicines, Synthon improves lives by enabling access to affordable medicines in a sustainable way. www.synthon.com



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