

## **Senores Pharmaceuticals acquires ANDA for Roflumilast 250 mcg and 500 mcg tablets**

**Atlanta, USA / Ahmedabad, India, 20th February 2025** – Senores Pharmaceuticals Limited ('SPL'), through its wholly-owned subsidiary Senores Pharmaceuticals, Inc., USA ('SPI'), has signed an agreement today to **acquire the USFDA-approved Abbreviated New Drug Application ('ANDA')** for **'Roflumilast' 250 mcg and 500 mcg tablets** from Breckenridge Pharmaceutical, Inc., a U.S. subsidiary of Towa International that markets, distributes, and sells generic pharmaceuticals in the United States.

Roflumilast is indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe Chronic Obstructive Pulmonary Disease (COPD) associated with chronic bronchitis and a history of exacerbations. The market size of Roflumilast in the USA was ~USD 32 Mn (MAT June 2024)\* as per IQVIA and ~USD 46 Mn (MAT September 2024)# as per the specialty data aggregator Symphony.

The acquisition will be funded through the Initial Public Offer ('IPO') proceeds raised by SPL. This is in line with the Objects of the IPO stated in the Red Herring Prospectus.

Commenting on the acquisition, **Mr. Swapnil Shah, Managing Director, Senores Pharmaceuticals Limited** said,

*"We are excited to announce the acquisition of the Roflumilast tablet ANDA from Breckenridge Pharmaceutical, Inc.*

*This strategic acquisition of Roflumilast Tablet ANDA, for which the manufacturing will be done locally at our US site, expands our portfolio into specialty distribution and also helps us establish a presence in the chronic bronchitis therapy area. This aligns with our strategic focus on identifying and entering a niche, under-penetrated generic formulations with an opportunity to serve the unmet needs in healthcare"*

\* Source: IQVIA Database

# Source: Symphony Database

**About Senores Pharmaceuticals Limited:**

Senores Pharmaceuticals Limited (“Senores”) is a global, research-driven pharmaceutical company engaged in developing and manufacturing a wide range of pharmaceutical products predominantly for the US, Canada, and other regulated and emerging markets across various therapeutic areas and dosage forms.

The companies’ current portfolio includes 24 ANDA and 21 CMO/CDMO commercial products that are permitted for distribution in the USA. Senores is also engaged in the development and manufacturing of complex generics certified by global food and drugs authorities and delivers generic drugs for emerging markets catering to more than 40 countries. The company has currently approval from regulatory bodies of more than 10 countries for its manufacturing facility in Chhatral for emerging markets with over 260 product registrations and 530 product applications. Senores also manufactures critical care injectables and Active Pharmaceutical Ingredients (API).

Senores has 2 manufacturing facilities for formulations – one in Atlanta, US which is USFDA approved and DEA/BAA compliant & other is in Chhatral, Ahmedabad, India approved by WHO-GMP to cater to emerging markets. The company also has 2 manufacturing facilities for API in India, both located around Ahmedabad, with one in Chhatral and the other in Naroda. Senores has strong R&D capabilities to drive differentiated product portfolio across 3 R&D sites (1 in the USA and 2 in India).

**Safe Harbor Statement:**

Statements in this document relating to future status, events, or circumstances, including but not limited to statements about plans and objectives, the progress and results of research and development, potential project characteristics, project potential and target dates for project related issues are forward-looking statements based on estimates and the anticipated effects of future events on current and developing circumstances. Such statements are subject to numerous risks and uncertainties and are not necessarily predictive of future results. Actual results may differ materially from those anticipated in the forward-looking statements. The company assumes no obligation to update forward-looking statements to reflect actual results changed assumptions or other factors.

**For more information, please contact:**

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