

**ALKEM LABORATORIES LTD.**

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10th October, 2024

To,

**The Corporate Relationship Department
BSE Limited**
Phiroze Jeejeebhoy Towers,
Dalal Street,
Mumbai 400 001.
Scrip Code: 539523

National Stock Exchange of India Limited
Exchange Plaza,
Bandra Kurla Complex,
Bandra East ,
Mumbai 400 051.
Scrip Symbol: ALKEM

Sub: Press Release – ALKEM signs a licensing agreement with M/s. Sonnet BioTherapeutics Holdings, Inc. to develop and commercialize SON-080 for Diabetic Peripheral Neuropathy in India.

Dear Sir(s)/Madam,

This is to intimate you that Alkem Laboratories Limited (the “Company”) has signed a licensing agreement with M/s. Sonnet BioTherapeutics Holdings, Inc. (“Sonnet”) to develop, manufacture and commercialize the drug candidate ‘SON-080’ for the treatment of Diabetic Peripheral Neuropathy (DPN) in India.

A press release in this regard is enclosed herewith.

Kindly take the same on record.

Sincerely,

For **Alkem Laboratories Limited**

Manish Narang

President- Legal, Company Secretary and Compliance Officer

Press Release

Alkem Laboratories enters into a licensing agreement with US-based Sonnet BioTherapeutics to develop and commercialise its drug candidate for diabetic peripheral neuropathy in India

- *Sonnet's drug candidate "SON-080" has shown encouraging data in phase 1b clinical trial*
- *Under the licensing agreement, Alkem will carry out the clinical development of "SON-080" in India to enable global and India regulatory filings*
- *Alkem has exclusive rights to develop, manufacture and commercialise the drug in India*

Mumbai, October 10, 2024: Alkem Laboratories Ltd. (BSE: 539523, NSE: ALKEM, "Alkem" and includes its associate companies and/or subsidiaries), has entered into a licensing agreement with US-based Sonnet BioTherapeutics Holdings, Inc ("Sonnet") to develop, manufacture and commercialise the drug candidate "SON-080" for the treatment of diabetic peripheral neuropathy in India.

"SON-080" is Sonnet's proprietary version of "atexakin alfa". It has shown encouraging data in phase 1b clinical trial. The drug candidate was demonstrated to be well-tolerated and the pain and quality of life survey results suggested a potential for rapid improvement of peripheral neuropathy symptoms and post-dosing durability, compared to placebo controls.

Under the licensing agreement, Alkem will carry out the clinical development of "SON-080" in India with support from Sonnet and enable global and India regulatory filings. Alkem has exclusive rights to develop, manufacture and commercialise the drug in India.

India is grappling with a substantial burden of diabetes-related complications with diabetic peripheral neuropathy being a major one. Diabetic peripheral neuropathy is notably widespread, affecting up to 62% of people with diabetes mellitus in India.¹ Diabetic peripheral neuropathy primarily affects the hands and lower limbs. It can result in a loss of protective sensation, making individuals more prone to unnoticed injuries, particularly to the feet. Over time, this can lead to the development of serious complications, including amputation.

Dr. Akhilesh Sharma, President and Chief Medical Officer of Alkem said, "We are pleased to partner with Sonnet for this programme. We believe "SON-080" is a unique asset that has demonstrated promising disease modifying potential for diabetic peripheral neuropathy with translational studies showing nerve regeneration. There is a large prevalence of diabetic peripheral neuropathy in India, which we believe underscores the need for the drug development in this territory and potential value."

¹ International Journal of Diabetes in Developing Countries (January–March 2024) <https://doi.org/10.1007/s13410-024-01313-9>

Pankaj Mohan, Founder and Chief Executive Officer of Sonnet, said, “We are excited to partner with Alkem and look forward to advancing “SON-080” into phase 2 clinical development. We believe that Alkem is the ideal partner with significant experience and expertise.”

“SON-080” has undergone many years of development and the previous clinical trials have generated safety data from over 200 patients. “SON-080” has demonstrated compelling preclinical efficacy data in both diabetic peripheral neuropathy and chemotherapy induced neuropathy, including the ability to prevent the development of neuropathy and reverse established neuropathy when assessed by nerve conduction, histological integrity and sensorimotor function measurements.

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About Alkem:

Alkem Laboratories Ltd. is a leading Indian pharmaceutical company with a legacy of 50 years in providing high quality medicines to patients. It is the fifth largest pharmaceutical company in the Indian market with a dominant position in the therapy areas of anti-infectives, gastrointestinal, pain management drugs and supplements. It also has a growing portfolio of products in chronic therapies such as diabetes, neurology, cardiology, dermatology and urology. It has 19 state-of-the-art manufacturing facilities and cutting-edge research and development (R&D) centers across India and the US to develop and manufacture generic formulations, active pharmaceutical ingredients (APIs) and biosimilars. Apart from India, the company has meaningful presence in the US, Latin America, Australia and several Asian countries. “Inspiring Healthier Lives” is at the core of the values and culture of the organisation and reinforces its steadfast commitment to global health improvement. For more information, please visit www.alkemlabs.com and follow us on [LinkedIn](#), [X](#), [Facebook](#), [Instagram](#).

About Sonnet BioTherapeutics:

Sonnet BioTherapeutics Holdings, Inc. is an oncology-focused biotechnology company with a proprietary platform for developing targeted biologic drugs with single or bifunctional action. Known as FHAB (Fully Human Albumin Binding), the technology utilizes a fully human single chain antibody fragment (scFv) that binds to and "hitch-hikes" on human serum albumin (HSA) for transport to target tissues. Sonnet's FHAB was designed to specifically target tumor and lymphatic tissue, with an improved therapeutic window for optimizing the safety and efficacy of immune modulating biologic drugs. FHAB platform is the foundation of a modular, plug-and-play construct for potentiating a range of large molecule therapeutic classes, including cytokines, peptides, antibodies and vaccines.

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