MOREPEN

40 Years of Excellence

Date: 28/09/2026

To,

National Stock Exchange of India Ltd.
Exchange Plaza, Bandra Kurla Complex,
Bandra (East), Mumbai- 400 051
Symbol: MOREPENLAB

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai- 400 001
Scrip Code: 500288

Sub.: Press Release – 'Morepen strengthens integrated CDMO capabilities with first U.S. ANDA submission'

Dear Sir/ Madam,

Please find enclosed press release with the title 'Morepen strengthens integrated CDMO capabilities with first U.S. ANDA submission'.

This is for your information and dissemination on your website.

Thanking you,

Yours faithfully,

For Morepen Laboratories Limited

Vipul Kumar Srivastava
Digitally signed by Vipul Kumar Srivastava
Date: 2026.09.28 08:26:48 +05'30'

Vipul Kumar Srivastava
Company Secretary
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Encl.: a/a

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Morepen strengthens integrated CDMO capabilities with first U.S. ANDA submission

Milestone advances Morepen's API-to-finished dosage development offering

- **First U.S. ANDA submitted for Sitagliptin Tablets USP in three strengths**
- **Strengthens formulation, bioequivalence and regulatory dossier capabilities**
- **Supports specialized CDMO opportunities across regulated markets**

Gurugram, 28th September 2026: Morepen Laboratories Limited has submitted its first Abbreviated New Drug Application (ANDA) to the U.S. Food and Drug Administration for **Sitagliptin Tablets USP in 25 mg, 50 mg and 100 mg strengths**. The submission extends the Company's established API and CDMO expertise into integrated finished dosage development and regulatory filing.

The Sitagliptin program brings together formulation development and scale-up, analytical method development and validation, impurity control, stability studies and manufacture of regulatory batches under GMP systems. It also incorporates bioequivalence strategy, coordination with contract research organizations and integration of development and study data into the regulatory dossier.

These capabilities strengthen Morepen's ability to support **specialized CDMO assignments spanning API development, finished dosage formulation and regulatory submission**, broadening the scope and complexity of customer programs it can undertake.

Mr. Sanjay Suri, Managing Director, Morepen Laboratories Limited said *"Capability building is central to Morepen's next phase of growth. Our first ANDA submission brings together the scientific, manufacturing and regulatory skills needed to take an API through finished dosage development to a U.S. filing,"*

Mr. Suri Further added, *"Alongside our planned Innovation Hub and investments in advanced chemistry and technology, this milestone strengthens our ability to undertake specialized CDMO assignments and build long-term development partnerships."*

Morepen intends to build on this foundation through customer development programs, technology transfer, co-development and licensing opportunities. These capabilities can also support product and dossier development for **regulated markets across Europe and Asia**, tailored to each jurisdiction's requirements.

Over time, the Company aims to explore differentiated formulations, including potential U.S. **505(b)(2) development programs**, subject to product-specific studies and regulatory requirements.

Sitagliptin is an established oral treatment for adults with Type 2 diabetes, belonging to the DPP-4 inhibitor class, commonly known as gliptins. Its innovator product, Januvia, recorded worldwide sales of approximately **US$1.604 billion in 2025**.[1] The relevant U.S. phosphate salt patent is

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scheduled to expire in **November 2026**, with associated paediatric exclusivity extending to **May 2027**; certain manufacturers have separate arrangements permitting earlier entry.[2]

Morepen currently estimates **24–36 months from submission** to progress towards approval and commercial supply, subject to FDA review, satisfactory completion of applicable formulation facility inspection requirements and applicable patent and exclusivity requirements.

About Morepen Laboratories Limited

Morepen Laboratories Limited (NSE: MOREPENLAB; BSE: 500288) is an Indian pharmaceutical company with established expertise in active pharmaceutical ingredients and a growing focus on contract development and manufacturing. The Company is expanding its scientific, manufacturing and regulatory capabilities to support integrated development programs and long-term partnerships with global pharmaceutical customers.

Notes to editors

1. **Market reference:** Merck's 2025 Annual Report records worldwide Januvia sales of US$1.604 billion. This represents historical innovator sales, rather than the total generic market or a forecast of Morepen's potential revenue.
2. **Patent reference:** The relevant U.S. sitagliptin phosphate salt patent is scheduled to expire on 24th November 2026, with associated paediatric exclusivity extending to 24th May 2027. Settlement arrangements permit certain manufacturers to enter earlier.
3. **Submission status:** ANDA No. 221758 was submitted on 25th September 2026. Submission does not constitute FDA acceptance for substantive review, product approval or authorization for U.S. commercial supply.
4. **Development pathways:** References to Europe, Asia and potential 505(b)(2) programs describe future development opportunities. Each program would require its own supporting data and applicable regulatory submissions and approvals.

Forward-looking statements

This release contains forward-looking statements concerning Morepen's development plans, proposed capabilities, potential partnerships, regulatory timelines and commercialization. These statements reflect current expectations and are subject to risks and uncertainties, including regulatory outcomes, facility inspections, development results, intellectual property requirements and market conditions. Actual outcomes may differ materially. The Company undertakes no obligation to update these statements, except as required by applicable law.

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