Innovating for
affordable healthcare

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Sub: Intimation U/R 30 of the SEBI (LODR) Regulations 2015- Reg.
Ref: Stock Code: NSE: SHILPAMED/BSE-530549

Shilpa Medicare Limited Completes Human Clinical Studies of High concentration Biosimilar Adalimumab

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Dear Sir / Madam,

This is to inform you that the Company, via its wholly owned subsidiary, Shilpa Biologicals Pvt Ltd (SBPL), has successfully completed the phase 3 Human Clinical studies of its first biosimilar, the 100mg/ml High Concentration (HC) Adalimumab biosimilar and has submitted the dossier to the CDSCO for review and grant of marketing/manufacturing license – a first in India.

The drug is expected to cater to the fast growing Rheumatoid Arthritis, Plaque Psoriasis, JIA, Psoriatic Arthritis, Ankylosing Spondylitis, Ulcerative Colitis, Crohns disease, HS and Uveitis markets – diseases where India has the largest patient populations.

While the actual dosage to the patients remains at 40mg and 80mg, the high concentration differentiated formulation of adalimumab enjoys the following advantages over the currently available 50mg/ml formulations –

a. Lower pain/inflammation at the site of injection due to -
    1. Elimination of local inflammation causing components in the HC formulation
    2. Lower volumes delivered for the same dosage, as compared to the older formulations.
    3. Lower viscosity as compared to the older formulations – contributing to ease of delivery.

b. In diseases like Crohns's Disease, Psoriasis, Ulcerative colitis, where the starting loading doses are high, the high concentration formulation turns out to be significantly more economical for patients and convenient for the doctors (as compared to the older formulations).

c. Compatibility with autoinjector is higher for this formulation. SBPL intends to also provide patients with the option of self dosing at home via an autoinjector soon.