

Intas launches DCGI-approved Tofacitinib Topical (JAKi) in Auto-Immune Condition Atopic Dermatitis (AD) for Indian patients.

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Intas Pharmaceuticals Ltd., one of India's leading pharmaceutical companies with operations across the globe has launched TOFATAS – a DCGI-approved, Tofacitinib Ointment 2% w/w for the treatment of mild to moderate Atopic Dermatitis (AD) in patients 18 years and above having flare-ups of the disease.

Atopic Dermatitis (AD) is a chronic inflammatory, non-communicable, and relapsing skin disease that most often develops in all age groups. Atopic Dermatitis is a multifactorial disease arising from a complex interaction between genetic, environmental, and immunological factors. Despite unmet needs, approximately 15 years have passed since a topical therapy with a new mechanism of action for atopic dermatitis (AD) has been introduced in India. The quality of life of the patients suffering from Atopic Dermatitis (AD) is compromised due to factors like consistent itching, sleep disturbances, poor performance at school/work, and disturbed social, mental, and emotional functioning.

Safety issues with existing therapies (Topical Corticosteroids/Topical Calcineurin Inhibitors) in the management of AD have always been a challenge in the long run as they are accompanied by increased risks of side effects which impact the patient's quality of life. Furthermore, due to the distinct characteristics of Atopic Dermatitis, its management remains a challenge.

"There have been no approved Topical JAK inhibitors in India available to date and the approval of TOFATAS OINTMENT 2%, therefore, would help in patients who desire a steroidfree topical agent for Atopic Dermatitis, and we hope that real-world data mirrors the approvals given to this agent in India," said Dr Kabir Sardana, MD, DNB, MNAMS, Professor (Dermatology) at the RML Hospital, Delhi. "Atopic Dermatitis is a chronic relapsing condition leading to poor quality of life and psychosocial complications. Current therapy has unmet needs. We welcome the DCGIapproved new topical Tofacitinib 2%, which will give new hope to these sufferers" said Dr Satish Udare, Senior Consultant Dermatologist, Thane/Navi Mumbai.

Dr Alok Chaturvedi (Associate Executive Vice President & Head-Medical Affairs, Intas) said "Intas being a frontrunner in dermatology therapy, boldly and successfully endeavoured to bridge this critical treatment gap by investing in extensive research efforts to develop and formulate TOFATAS Ointment - a drug that delivers the desired outcome and the clinical benefits for Atopic Dermatitis patients. A Phase III clinical study of TOFATAS (Tofacitinib Ointment 2% w/w) in Atopic Dermatitis patients in India showed remarkable safety and efficacy."

About Intas Pharmaceuticals Limited

Intas Pharmaceuticals Ltd. is a leading, vertically integrated, multinational pharmaceutical company based in Ahmedabad, India, having end-to-end capabilities of formulation development, manufacturing, and marketing along with backward integration of Active Pharmaceutical Ingredients (API). The organization has more than 19,000 employees, 14 highly advanced manufacturing sites worldwide and sells products in more than 85 countries. Intas' revenue amounted to USD 2.5 bn in FY 2021-22 and the compounded annual growth rate of revenue has been 22% in the past 5 years.

For more information, please visit www.intaspharma.com.