Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

Volume: 12 ***Number:22*** ***27th January 2019***

Content

Editorial

Recent declaration of formation ofNational Medical Devices Promotion Council by the Minister of Commerce and Industry, Govt. of India under Dept of Industry Policy and Promotion (DIPP) will certainly give a fillip to the growth of Medical Devices manufacturing in India. It is expected to end the 70-90 percent import dependence of Indian medical devices industry and an import bill of about 31000 crores. Minister also announced establishing a Medical Devices Design Centre and assured as exports picks up by establishing a Medical Devices Exports Promotion Council like - Pharmexcil. This new body will act as a facilitating and promotion and developmental body for the Indian Medical Devices Industry.

It is expected that Medical Devices Development Council will help realizethe expectation for India to be among the Top 5 Medical Devices manufacturing hubs worldwide as the Council will spearhead the policy needs to accelerate the manufacturing of medical devices in India. Experts are happy to find that the Govt. is taking serious steps to make India a global robust hub for medical devices manufacturing and fulfilling Govt's ambitious mission of making quality healthcare affordable for common masses.

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New Drug: Tildrakizumab for psoriasis
Approved indication: psoriasis

Ilumya (Sun)
pre-filled syringes containing 100 mg/mL
Australian Medicines Handbook section 8.2, Drugs for psoriasis

Immune mechanisms are involved in the inflammation seen in psoriasis. Several pro-inflammatory cytokines, such as the interleukins, are implicated and this has led to the use of cytokine modulators when the psoriasis is severe enough to require systemic therapy. These include tumour necrosis factor alpha antagonists, such as etanercept, and the monoclonal antibodies ixekizumab, secukinumab and ustekinumab. Tildrakizumab is a monoclonal antibody which blocks the interaction of interleukin 23 with its receptor and this inhibits the release of pro-inflammatory cytokines.

Tildrakizumab has to be given by subcutaneous injection. The drug is slowly absorbed. In the recommended regimen of one injection followed by another after four weeks and then every 12 weeks, steady-state concentrations are reached at 16 weeks. The antibody is catabolised with a half-life of 23 days. No studies have been done in patients with hepatic or renal impairment.

A phase II trial studied several different doses of tildrakizumab in 355 patients with moderate–severe plaque psoriasis. To be included in the trial the patients had to have a Psoriasis Area and Severity Index (PASI) score of at least 12 (moderate severity). After 16 weeks this score had reduced by at least 75% in 33–74% of the patients. This response was significantly better than the 4% rate seen in a placebo group. At the recommended dose of tildrakizumab 100 mg, 62% of the patients had cleared or minimal psoriasis.[1]

The main trials of tildrakizumab (reSURFACE 1 and 2) studied doses of 100 mg and 200 mg in patients with moderate–severe plaque psoriasis (PASI score ≥12). The participants in reSURFACE 1 were randomised to tildrakizumab or placebo, while in reSURFACE 2 patients were randomised to tildrakizumab, etanercept or placebo. After 12 weeks the patients in the placebo groups were re-randomised to one of the tildrakizumab groups. The PASI score fell by at least 75% (PASI 75) in 6% of the placebo groups at 12 weeks. In contrast, this outcome was achieved by 61–64% of the patients given tildrakizumab 100 mg, 62–66% of those given 200 mg and 48% of the etanercept group. At 28 weeks the PASI 75 outcome was achieved by 73–82% of the patients who continued tildrakizumab and 54% of those taking etanercept. Favourable responses were also seen in 55–86% of the patients who switched from placebo. With tildrakizumab 100 mg, the psoriasis was clear or minimal in 55–58% of the patients at 12 weeks and in 65–66% of those who were treated for 28 weeks.[2]

During the phase III trials only about 1% of the patients discontinued tildrakizumab 100 mg because of adverse effects.[2] Common effects included injection-site reactions, nasopharyngitis and fatigue. Injecting an antibody that alters the immune response has some potentially serious adverse effects. Cancer was more frequent with tildrakizumab than placebo (0.2 vs 0%). During treatment 6.5% of the patients developed antibodies to tildrakizumab. This led to minor decreases in efficacy, but no apparent increase in adverse events. Tuberculosis should be excluded before treatment. Live vaccines should not be given during treatment and for at least 17 weeks afterwards.

In all clinical trials, 1994 people received tildrakizumab and the mean duration of treatment was 53.9 weeks. As psoriasis is a chronic disease, longer term safety data will be needed, including safety in pregnancy and lactation. Although the efficacy of tildrakizumab is probably similar to that of other monoclonal antibodies, its onset of action is slower. More patients will achieve a PASI 75 response with tildrakizumab than with etanercept, but the difference in patients with minimal or cleared psoriasis at 12 weeks is not statistically significant.[2]

References

1. Papp K, Thaçi D, Reich K, Riedl E, Langley RG, Krueger JG, et al. Tildrakizumab (MK-3222), an anti-interleukin-23p19 monoclonal antibody, improves psoriasis in a phase IIb randomized placebo-controlled trial. Br J Dermatol 2015;173:930-9.
2. Reich K, Papp KA, Blauvelt A, Tyring SK, Sinclair R, Thaçi D, et al. Tildrakizumab versus placebo or etanercept for chronic plaque psoriasis (reSURFACE 1 and reSURFACE 2): results from two randomised controlled, phase 3 trials. Lancet 2017;390:276-88.

Reference: Australian Prescriber

Abbott, malaria nonprofit work toward disease elimination in Odisha, India

India launched a five-year program in 2017 called the National Strategic Plan for Malaria Elimination, and this year Abbott, in partnership with nonprofit Malaria No More and the government of the state of Odisha in eastern India, will collaborate toward that goal. Abbott will donate $750,000 over a three-year period, 1 million rapid diagnostic tests and technical expertise to boost the state's malaria surveillance and detection.

Ref.: Seeking Alpha

FDA orphan status granted to 3 Cerecor candidates

The FDA has given orphan drug designations to Cerecor's D-galactose and D-mannose, which are indicated for phosphoglucomutase 1 deficiency and mannose phosphate isomerase deficiency, respectively. The company's L-fucose, being developed for congenital disorder glycosylation IIc, was also given orphan status.

Ref.: Seeking Alpha

Australia OKs plitidepsin-dexamethasone combo for multiple myeloma

The Therapeutic Goods Administration of Australia approved PharmaMar'sAplidin, or plitidepsin, combined with dexamethasone, as a treatment for patients with relapsed or refractory multiple myeloma. Eligible patients will have access to Aplidin for free through a Compassionate Access Program.

Ref.: Myeloma Research News

NPPA cuts prices of cancer, HIV, cardiac drugs by around 25%

Prices of 24 essential drugs used for treatment of cancer, human immunodeficiency virus (HIV), bacterial infections, anxiety and cardiac conditions have been capped by the government, reducing the cost by an average of around 25%.

“National Pharmaceutical Pricing Authority (NPPA) has fixed/revised ceiling prices of 24 scheduled formulations of schedule-I under Drugs (Price Control) Amendment Order, 2016," the drug pricing regulator said in a order on its website.

It has also capped the retail price of 31 formulations under Drug Price Control Orders (DPCO), 2013, NPPA said. “The prices of 24 drugs have been reduced on an average of 25%. In some cases the reduction is 10 to 15% while for others it is up to 30 to 35%," NPPA chairman Bhupendra Singh told PTI.

The government fixes the prices of essential drugs based on the simple average of all medicines in a particular therapeutic segment, having sales of more than 1%. It also monitors the maximum retail prices (MRP) of all the drugs and companies are allowed to hike prices of non-scheduled drugs by up to 10% in a year.

The government had notified DPCO, 2013, which covers 680 formulations, with effect from May 15, 2014, replacing the 1995 order that regulated prices of only 74 bulk drugs. Set up in 1997, NPPA has been entrusted with the task of fixation/revision of prices of pharma products, enforcement of provisions of the Drugs (Prices Control) Order and monitoring of prices of controlled and decontrolled drugs.

India removes price caps on foreign-made drugs to treat rare diseases

*I*n a controversial move intended to help patients gain access to new drugs, India has exempted from price controls foreign-made pharmaceuticals for treating rare diseases such as cystic fibrosis and muscular dystrophies. Drugs to treat such diseases are sometimes called orphan drugs in India. The exemption lasts for five years and applies to medicines patented in India and produced anywhere abroad. Previously, price-cap exemptions applied only to new drugs developed through R&D in India and produced there. India's Department of Pharmaceuticals expanded the price-cap exemption despite the concerns of Secretary of Health and Family Welfare Preeti Sudan, who wrote to Secretary of Pharmaceuticals Jai Priye Prakash in November 2018 asking for increased price controls. Other critics of the expanded exemption include domestic drug makers and public-health advocates. The decision was "hasty and ill-conceived," will reduce access to high-priced drugs, and will constrain the government's ability to act in the interest of public health, says Malini Aisola of the All-India Drug Action Network, which advocates for increased access to essential medicines. India's Ministry of Health & Family Welfare determines which diseases qualify as rare.

Sofosbuvir-based generic DAAs tested in patients with HCV, CKD

Details from a study by Indian researchers published in Liver International showed that treatment of patients with hepatitis C virus infection who have also been diagnosed with chronic kidney disease using generic sofosbuvir-based direct-acting antivirals proved very effective, even among those with advanced CKD and those undergoing dialysis. Sustained virological response was attained at 12 weeks in 100% of the patients after treatment was stopped in three groups that received full doses of sofosbuvir combined with either ribavirin, ledipasvir or daclatasvir.

Ref.: Medscape (free registration).

Temperature-Stable Experimental Tuberculosis Vaccine Enters Clinical Testing

An NIAID-supported Phase 1 clinical trial testing a freeze-dried, temperature stable formulation of an experimental TB vaccine regimen is ongoing at the Saint Louis University School of Medicine Center for Vaccine Development. The experimental vaccine, called ID93, was developed by scientists at the Infectious Disease Research Institute in Seattle. Investigators are examining if a powder formulation combining the vaccine and the adjuvant GLA-SE in a single vial, reconstituted with sterile water, is as effective at inducing an immune response in participants as the previously-tested two-vial combination of powdered ID93 and liquid GLA-SE.

Ref.: National Institute of Allergy and Infectious Diseases

Forthcoming Event

6th International Congress of Society For Ethnopharmacology

8-10 February 2019

Manipal, India