Boulogne-Billancourt, 26th July 2018

IPSEN'S CELL-BASED ASSAY RECEIVES APPROVALS IN THE E.U. AND SWITZERLAND FOR ITS BOTULINUM TOXIN

Ipsen has received an approval from competent regulatory authorities in the E.U. and Switzerland for the in vitro Cell-Based Assay (CBA) for establishing the stability and the potency of its products DYSPORT® and AZZALURE®[1].

Ipsen produces a prescription drug containing a botulinum toxin type A. It is primarily used for the treatment of a wide range of neurological conditions in which patients can experience uncontrollable, severely debilitating and sometimes painful muscle spasms.

To ensure drug efficacy and patient safety, regulatory authorities worldwide request that all manufacturers of botulinum toxins establish the potency of each batch that they release.

The Cell-Based Assay is meant to replace the mouse-based LD50 assay and will lead to a drastic reduction of animal-based testing.

Ipsen will implement the Cell-Based Assay for products supplied to the E.U. and Switzerland in the shortest achievable timeframe.

Ipsen continues to work to secure the fastest possible approval from regulatory agencies worldwide.

This major milestone is the result of Ipsen's commitment to animal welfare and extensive investments in the research and development of an in vitro Cell-Based Assay that could achieve a level of precision comparable to the mouse-based LD50 assay.

[1] Marketed in partnership with Galderma.

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