

Boulogne-Billancourt, 25th February 2020

IPSEN'S CELL BASED ASSAY FOR ITS BOTULINUM TOXIN IS NOW IMPLEMENTED FOR THE U.S. & CANADA

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.

In 2019, Ipsen received approvals from regulatory authorities in the U.S. and Canada for the *in-vitro* Cell-Based Assay (CBA) for establishing the stability and the potency of its botulinum toxin products. This added to the approvals from the E.U. and Switzerland already in place for products DYSPORT® (botulinum toxin type A) and AZZALURE®¹ (botulinum toxin type A).

Ipsen's Cell-Based Assay is now fully implemented for its botulinum toxin products DYSPORT® (botulinum toxin type A) and AZZALURE® (botulinum toxin type A) supplied to the U.S., Canada, E.U. and Switzerland.

Ipsen continues to work to secure the fastest possible approval from the final few remaining 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.

Ipsen may be compelled to revert temporarily to the mouse-based LD50 assay as a back-up testing method under exceptional circumstances where patient supply might otherwise be impacted and in compliance with regulatory requirements.

¹ Marketed in partnership with Galderma.