Boulogne-Billancourt, 17th June 2019

IPSEN'S CELL BASED ASSAY ADDS APPROVALS IN THE U.S. & CANADA FOR ITS BOTULINUM TOXIN

Ipsen has 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 adds to the approvals from the E.U. and Switzerland already in place for 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.

Ipsen will implement the Cell-Based Assay for its botulinum toxin products supplied to the U.S. and Canada in the shortest achievable timeframe. Meanwhile, the Cell-Based Assay is now fully implemented for its products DYSPORT® and AZZALURE® supplied in the E.U. and Switzerland.

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.

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.

IPSEN PHARMA
65, QUAI GEORGES GORSE – 92100 BOULOGNE-BILLANCOURT – FRANCE
S.A.S. AU CAPITAL DE 5 856 055 €, R.C.S. NANTERRE 308 197 185 - CODE APE 4646Z, TVA FR 80 308 197 185
TÉLÉPHONE : +33 (0)1 58 33 50 00 - FAX : +33 (0)1 58 33 50 01
WWW.IPSEN.COM