Meeting with LEO Pharma

10 February 2014

List of attendees:

[**ART 4.1b**] (LEO Pharma); [**ART 4.1b**] (LEO Pharma)

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Summary:

On 10 February, the European Commission met with representatives of LEO Pharma, a small-medium sized pharmaceutical company based in Denmark owned by a foundation - to discuss the Transatlantic Trade and Investment Partnership (TTIP). Leo Pharma is not a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA). The Commission gave a general overview of the content and timing of negotiations and the industry presented its recent position paper jointly elaborated with Novo Nordisk, Lundbeck and the Danish Association of the Pharmaceutical Industry (Lif). The priorities outlined relate mainly to regulatory convergence, Intellectual Property Rights, clinical data transparency and enhanced transparency around market access for pharmaceuticals.

Regulatory Convergence

Overall, Leo Pharma is pleased that a constructive dialogue is already in place between the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) but would welcome a more formalised structure for it. More specifically, there are some key areas where greater regulatory convergence could be achieved and would bring efficiency gains.

The topmost priority regards mutually recognising Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) inspections. The Commission confirmed that this is in line with the EU priorities for the TTIP Agreement and believes that it is crucial to follow the progress of the FDA's internal reflections on its own ability to rely on foreign inspections.

Secondly, Leo Pharma would welcome harmonisation of paediatric study requirements as this would help avoiding duplication of clinical trials involving children and fostering global paediatric development. To this end, the industry calls for alignment on a common design for trials as well as common timelines and formats for submission of paediatric plans

While companies are entitled to apply for parallel scientific advice with the EMA and the FDA since a number of years, Leo Pharma would welcome a further step in the direction of setting up a Joint Scientific Advice. In fact, the current procedure does not give any guarantee that independent advices will be similar and Leo Pharma feels that, notwithstanding the right of both agencies to have different views, the EMA and the FDA should at least consider each other's advices and companies shall have a better insight of why opinions are divergent. Leo Pharma agreed to provide more specific examples after consulting the Regulatory Department. Clinical trials constitute a significant investment for companies and with no

harmonisation there are unnecessary duplications and delays in placing products in the markets, and therefore delayed patients' access to treatments.

If the idea of having a Regulatory Cooperation Council is formalised, Leo Pharma feels that pharmaceutical issues should be included in its work as to ensure continuous collaboration in this field between EMA and FDA even after the end of the negotiations.

As both Parties are developing Coding and serialisation systems, Leo Pharma would welcome alignment in this field considering both the global character of supply chains and the benefits in terms of patient safety. The EU is in the process of elaborating its system and will share its progress with the FDA at due stage.

When discussing Biosimilars, Leo Pharma raised the issue of biosimilar trade names which in their view shall not be identical to the trade name given to the reference biologic medicine as this could also compromise pharmacovigilance. Leo Pharma reported that patients associations in the US have asked for distinguishable trade names for biosimilars and respective biologics in the context of a public hearing in the matter.

Intellectual Property Rights (IPRs)

Leo Pharma recognises that both the EU and the US uphold high levels of protection and would welcome the Parties to continue promoting strong IPRs and taking a similar approach when negotiating with third countries.

Clinical Data Transparency

Leo Pharma supports transparency but would welcome more consistent EU/US approaches to requirements for pre-marketing authorisation publications of clinical trials data. Though generally positive about sharing data, Leo Pharma referred to the new EMA policy and the concerns that may arise in terms of scientific journals not publishing data already disclosed and of possible consequences when applying to the FDA.

Market Access Requirements for pharmaceuticals

The main issue related to market access is ensuring that decisions regarding pricing and reimbursement policies and procedures are evidence-based and transparent. This request has been already put forward with strong interest by the US pharmaceutical industry. Commission noted the strikingly different proportion of public health coverage in the two sides of the Atlantic and possible reserves from some Member States in Europe. Leo Pharma noted that although interested in the matter this is not be the most urgent priority to address in the context of the TTIP.