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Mundipharma strengthens position as a leader in biosimilars with acquisition of development company Cinfa Biotech

- Deal includes global rights to pegfilgrastim biosimilar, Pelmeg® with a potential global market worth $4.5bn[1]
- Mundipharma acquires 100% ownership from parent company Infarco
- As a leader in biosimilars in Europe, today's deal deepens Mundipharma's biosimilars platform beyond commercial excellence to development
- Mundipharma estimates that through its existing partnership with Celltrion – Remsima® and Truxima® have saved healthcare systems approximately €330m[2]

Cambridge, UK, 10th October 2018. The Mundipharma global network of independent associated companies has today added development capabilities to its biosimilars platform with the purchase of biosimilars development company Cinfa Biotech.

The announcement sees the Mundipharma network (including NAPP Pharmaceuticals in the UK) gain immediate access to Pelmeg® (B12019), a biosimilar to Neulasta® (pegfilgrastim), which received CHMP recommendation for approval on 20th September 2018.

Alberto Martinez, President and CEO, Mundipharma International Ltd, "*Our biosimilars platform is a key component of our growth strategy and today's acquisition is the obvious next step in us ensuring we remain agile and innovative in the biosimilars space.*

"We have successfully demonstrated our commercial excellence in biosimilars by building a market leading platform. Through our partnership with Celltrion on Remsima® and Truxima® we estimate savings for healthcare systems of approximately €330m[2] from launch to the end of 2017. By acquiring Cinfa Biotech we have now taken the first step in our plans to, not only expand our biosimilars footprint, but to develop future biosimilars which will continue to afford healthcare systems further savings and, in some cases, wider access for patients."

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Pelmeg® (originator Neulasta®[3]) is a pegylated version of granulocyte-colony stimulating factor (G-CSF) for the treatment of chemotherapy-induced neutropenia that works by stimulating the bone marrow to produce more neutrophils, thereby reducing the incidence of infection.

With a non-US market worth of $603mllion[1] and originator patents already expired, pegfilgrastim biosimilars offer an exciting market opportunity.

Enrique Ordieres, President of Infarco the parent company of Cinfa Group, commented, "*After having successfully developed and manufactured our first biosimilar, we strongly believe Mundipharma is best placed to take Pelmeg® forward through the Cinfa Biotech acquisition. They have the pedigree and proven track record of launching biosimilars in Europe, have built strong partnerships with payers, hospital specialists and decision makers and have the deep local understanding of complex tender environments.*"

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Notes to editors:

About the Mundipharma network

The Mundipharma global network of privately-owned independent associated companies was founded in 1956 by doctors, and now operates in over 120 countries worldwide. We are focused on developing business partnerships to identify and accelerate meaningful technology across an increasingly diverse portfolio of therapy areas including respiratory, oncology, pain, and biosimilars. Consistent with our entrepreneurial heritage, we like to think we see what others don't by challenging conventional wisdom and asking different and challenging questions. By working in partnership with all our stakeholders, the Mundipharma network develops medicines that create value for patients, payers and wider healthcare systems.

For more information please visit: www.mundipharma.com.

About Cinfa Biotech

Cinfa Biotech was created in 2013 as part of the Spanish Cinfa Group. The company conduct biosimilars development and manufacturing exclusively in Europe. Highest European quality standards based on strict guidelines and their specialist know-how are the key to their success in the global biosimilars market.

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They currently have two product candidates in development including: Cinfa Biotech's lead product candidate, pegfilgrastim, a biosimilar version of Neulasta® (INN: pegfilgrastim) to treat chemotherapy-induced neutropenia. Pegfilgrastim, a granulocyte colony-stimulating factor (G-CSF) receptor agonist, is used to stimulate bone marrow to produce more neutrophils in order to decrease the incidence of infection in patients undergoing chemotherapy.

About biosimilars

Biosimilar is a term used to describe officially approved subsequent versions of biopharmaceutical medicines that are made available by a different company following patent and exclusivity expiry on the original product. Biosimilars are classed as biologic medical products, which mean they contain an active drug substance that is comprised of, or derived from, a living organism.

Biosimilars are strictly regulated and need to demonstrate comparability to the previously approved reference product via a thorough development programme including quality, nonclinical and clinical data.

Remsima® (infliximab) and Truxima® (*i.v.* rituximab) are both registered trademarks of Celltrion, Inc. and are used under licence.

Neulasta® is a registered trademark of Amgen, Inc.

Pelmeg® is a registered trademark of Cinfa Biotech, S.L.

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References:

[1] Sales of Neulasta® in 2017: data from Amgen 2017 Fourth-quarter results (Global: $4,534 million. ROW: $603million). ROW sales: Available from: https://www.amgen.com/media/news-releases/2018/02/amgen-reports-fourth-quarter-and-full-year-2017-financial-results/

[2] Figure based on Mundipharma data - Biosimilar savings: Truxima and Remsima net price vs originator list price x units or vials sold. Time periods are from launch, with data based on five markets for Remsima and six markets for Truxima through to year end 2017.

[3] Neulasta® patient information leaflet. Available from: https://www.medicines.org.uk/emc/product/6770/pil