Mundipharma to launch *Truxima*®▼ (rituximab), the first biosimilar monoclonal antibody for the treatment of cancer, in seven European markets

- *Truxima® has been authorised for use by the European Commission (EC)[1], making it the first biosimilar monoclonal antibody licensed for the treatment of cancer[2]*
- *Truxima has been approved for use in all indications of the reference product Mabthera®[3], based on its preclinical, safety and efficacy data*
- *Truxima is expected to cost less than the reference product and the hope is that these savings could potentially free up budgets for other innovative cancer medications*
- *It is estimated that, in total, biosimilars have the potential to save European healthcare systems approximately €15 billion over the next five years[4]*

Cambridge, UK. 22 February 2017. – Mundipharma and its network of independent associated companies will launch Truxima (rituximab) in the UK, Germany, Italy, Netherlands, Belgium, Republic of Ireland and Luxembourg, following authorisation by the EMA. Truxima is the first biosimilar monoclonal antibody authorised by the European Commission (EC) for the treatment of cancers, [i] including diffuse large B-cell lymphoma, follicular lymphoma and chronic lymphocytic leukaemia.[1,2]

The marketing authorisation of Truxima was granted by the EMA on the basis of a rigorous comparability exercise that included preclinical and clinical testing. As a result, it has been demonstrated via quality, nonclinical and clinical data that all major physicochemical characteristics and biological activities of Truxima were comparable to those of the reference product. Like the reference product, Truxima is therefore authorised for the treatment of diffuse large B cell lymphoma, follicular lymphoma, chronic lymphocytic leukaemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis.[2]

Monoclonal antibodies are biologics – large, complex molecules isolated from natural sources, human, animal or microorganism. Biologics have led to significant improvements in the treatment of cancers since their introduction in 1998, but growing usage has resulted in a high financial burden on European healthcare systems at a time when newer innovative cancer therapies are also competing for funding in cost conscious times.

[i] See: *Notes to editors: About Truxima* for full list of licence indications

In 2015, the reference product (Mabthera) was the world's top selling cancer drug, costing healthcare systems over US$7.1billion worldwide.[5] As Truxima is intended to cost less than the reference product, it is hoped that cost savings from using a biosimilar rituximab will enable access for patients in need of new innovative cancer therapies.[6]

Truxima is the second biosimilar monoclonal antibody to be marketed and distributed by the Mundipharma network in Europe, having launched infliximab, the first biosimilar monoclonal antibody, in 2015.

"Mundipharma is constantly seeking opportunities to develop and commercialise sustainable, responsible medicines for a complex and cost conscious world," said Antony Mattessich, Managing Director, Mundipharma International Limited. "With our global reach, European expertise and proven track record, we are an attractive partner for any companies looking to commercialise biosimilars in Europe and are looking forward to further expand our portfolio in this complex and rapidly growing area."

-Ends-

Notes to editors

About Mundipharma

Mundipharma International Limited is part of a global network of privately-owned independent associated companies founded in 1956 by doctors, now operating in over 70 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, addiction therapy and inflammatory conditions. 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 further information please visit: www.mundipharma.com

About Truxima

Truxima is a genetically engineered chimeric murine/human monoclonal immunoglobulin G1 kappa antibody assessed by the EMA as a rituximab biosimilar. The therapeutic indications as well as the dosing regimen for Truxima will be the same as those of the reference rituximab product. As such, Truxima is indicated for: [2]

Non-Hodgkin lymphoma (NHL)	Follicular lymphoma (FL)	• Previously untreated stage III – IV FL in combination with chemotherapy[1,2] • Maintenance therapy in patients responding to induction therapy[1,2] • Monotherapy in stage III – IV FL patients who are chemoresistant or are in their second or subsequent relapse after chemotherapy
	Diffuse large B-cell lymphoma (DLBCL)	CD20+ DLBCL in combination with CHOP chemotherapy
	Chronic lymphocytic leukaemia (CLL)	Previously untreated and relapsed/refractory CLL in combination with chemotherapy
Rheumatoid arthritis (RA)		In combination with methotrexate, for adult patients with severe active RA who have had an inadequate response or intolerance to other DMARDs including at least one anti-TNF therapy
Granulomatosis with polyangiitis and microscopic polyangiitis		In combination with glucocorticoids for the induction of remission in adults with severe active granulomatosis with polyangiitis and microscopic polyangiitis

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 means 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.

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