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NICE Recommends Chugai's RoACTEMRA® (tocilizumab) as Monotherapy for Treatment of Severe Rheumatoid Arthritis

TOKYO, September 18, 2015 --Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama] (Chugai) (TOKYO: 4519) announced today that National Institute for Health and Clinical Excellence(NICE) issued a positive Final Appraisal Determination(FAD), recommending RoACTEMRA® (tocilizumab) monotherapy for use on the National Health Services (NHS) on September 3, 2015.[1]

The decision is based on a dossier of data that included results which show RoACTEMRA helps almost four times as many patients achieve remission than those treated with a leading anti-TNF monotherapy.[3] As many as 20,000 patients in England and Wales with severe rheumatoid arthritis (RA) could soon benefit from RoACTEMRA monotherapy.[2] The guidance brings England and Wales in line with Scotland, where RoACTEMRA has been available as monotherapy to Scottish patients for a year.[4]

RoACTEMRA is a first of its kind biologic and the only interleukin-6 (IL-6) receptor antagonist licensed for the treatment of patients with severe RA.[5] Biologics are used by as many as 60% of patients who do not respond to conventional drugs (called conventional disease-modifying anti-rheumatic drugs or cDMARDs).[6] Biologic treatments are often given in combination with methotrexate; this positive determination for RoACTEMRA as monotherapy is an important step forward in the care of patients with severe RA as more than one third of patients are unable, or do not wish to take methotrexate.[2]

"We are delighted that NICE has recommended RoACTEMRA monotherapy treatment." said John Halls, Managing Director of Chugai Pharma Marketing Ltd., a wholly owned subsidiary of Chugai. "This recommendation indicates the high medical need of RoACTEMRA in monotherapy which is equivalent to outcomes of RoACTEMRA in combination with methotrexate. I believe the NICE recommendation will bring good news for RA patients who are intolerant to methotrexate or DMARDs."

RoACTEMRA monotherapy has been recommended by NICE, in addition to its current use in combination with methotrexate, for the treatment of patients with severe RA whose disease has not responded to intensive therapy with a combination of cDMARDs.[1] Data from a key Phase 4 trial (ADACTA), which formed part of the submission to NICE, showed that RoACTEMRA IV monotherapy helps almost four times as many severe RA patients, for whom methotrexate is deemed inappropriate, achieve remission compared to patients treated with a commonly used anti-TNF monotherapy, adalimumab (DAS28<2.6 (remission)

39.9% versus 10.5%, CI 3.1-10.3, p<0.0001).[3] In addition, mean change of DAS28 was significantly greater for RoACTEMRA (-3.3) compared with adalimumab (-1.8) (difference -1.5, CI -1.8 to -1.1, p<0.0001), highlighting the superiority of RoACTEMRA IV monotherapy over adalimumab monotherapy for reduction of signs and symptoms of RA.[3] The most commonly reported adverse events for RoACTEMRA are upper respiratory tract infections and nasopharyngitis (common cold). The number of serious adverse events was similar between the medicines.[3]

About rheumatoid arthritis (RA)

RA is a chronic, progressive and disabling disease which affects over 690,000 adults in the UK and the incidence is rising.[7] The disease often starts during the prime of a person's working life, between the age of 30 and 50,[8] and around 50% of people with RA will be unable to work within ten years due to disability.[9]

Fast facts:

- Nearly 1 in 100 people will develop RA[10]
- Women are almost three times more likely to suffer RA than men[11]
- The average life expectancy of people with RA is shortened by 3-7 years[12]
- The estimated cost to the UK economy of sick leave and work-related disability for RA is £1.8 billion a year and RA costs the NHS £560 million a year[11]

About RoACTEMRA/ACTEMRA(tocilizumab)

Launched in the UK in 2009 as the first interleukin-6 (IL-6) receptor antagonist,[5] RoACTEMRA, known as ACTEMRA in the U.S., is licensed in England and Wales for use in combination with methotrexate for the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.[5] The treatment can be given as a monotherapy to adult patients in the case of intolerance to methotrexate or where continued treatment with methotrexate is inappropriate.[5]

In Scotland, RoACTEMRA has been reimbursed by the Scottish Medicines Consortium (SMC) for use in combination with methotrexate or as a monotherapy for Scottish patients.[4]

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