GSK provides update on ContRAst phase III programme for otilimab in the treatment of moderate to severe rheumatoid arthritis

PUBLISHED OCT 27, 2022
BY GSK

For media and investors only

GSK plc (LSE/NYSE: GSK) today provided an update on the ContRAst phase III programme for otilimab, an investigational monoclonal antibody targeting granulocyte-macrophage colony-stimulating factor (GM-CSF), in the potential treatment of moderate to severe rheumatoid arthritis (RA). The ContRAst phase III programme enrolled a broad range of difficult-to-treat patients who had an inadequate response to or could not tolerate available treatments.

ContRAst-1 and ContRAst-2 met their primary endpoints of a statistically significant ACR20 response versus placebo at week 12 in patients with inadequate response to methotrexate (ContRAst-1) and conventional synthetic or biologic disease modifying antirheumatic drugs (DMARDs) (ContRAst-2).

Data from ContRAst-3, the third trial in the programme, did not demonstrate statistical significance on the primary endpoint of ACR20 response versus placebo at week 12 in patients with inadequate response to biologic DMARDs and/or Janus Kinase inhibitors.

While the ContRAst-1 and ContRAst-2 trials met their primary endpoints, the efficacy demonstrated is unlikely to transform patient care for this difficult-to-treat patient population. Assessment of efficacy and safety data from the ContRAst programme is ongoing, however the limited efficacy demonstrated does not support a suitable benefit/risk profile for otilimab as a potential treatment for RA. As a result, GSK has decided not to progress with regulatory submissions.

Full results from the ContRAst phase III programme will be submitted for publication in 2023.

About the ContRAst phase III programme

The ContRAst phase III programme was designed to compare the efficacy and safety of two doses of otilimab (90mg and 150mg subcutaneous weekly injection) with placebo, tofacitinib (5mg capsules twice daily) and sarilumab (200mg subcutaneous injection every other week), all in combination with methotrexate or conventional DMARDs. The primary endpoint for each trial (ContRAst-1, ContRAst-2 and ContRAst-3) was the proportion of patients achieving ACR20 at week 12 (versus placebo).

RA is a chronic, systemic inflammatory condition characterised by pain, joint swelling, stiffness, joint destruction and disability. It is estimated to affect 24.5 million people globally. Despite the use of DMARDs, a substantial proportion of patients either fail to respond or have an inadequate response, indicating a need for more effective treatments with an alternative mechanism of action.

Otilimab (previously GSK3196165) is a fully human monoclonal antibody that inhibits granulocyte-macrophage colony-stimulating factor (GM-CSF), a protein that plays a central role in a broad range of immune-mediated diseases, including RA. GM-CSF acts on cells, including macrophages (an immune cell type that plays a key role in the inflammatory process), leading to inflammation, joint damage and pain. Otilimab neutralises the biological function of GM-CSF by blocking the interaction of GM-CSF with its cell surface receptor. Otilimab is not currently approved for use anywhere in the world.

GSK assumed exclusive worldwide responsibility of otilimab from MorphoSys AG in 2013 for all development and commercialisation activities in all therapeutic fields.

GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com/company.

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this

announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2021, GSK's Q2 Results for 2022 and any impacts of the COVID-19 pandemic.

ACR20 is defined by the American College of Rheumatology as a 20 percent improvement in both tender and swollen joint counts, plus three of the following: patient assessments of pain, global disease activity and physical function, physician global assessment of disease activity and acute phase reactant (high sensitivity c-reactive protein).

GBD 2015 Disease and Injury Incidence and Prevalence, Collaborators.

> Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990-2015: a systematic analysis for the Global Burden of Disease Study 2015

. Lancet (2016). 388 (10053): 1545–1602.

Press release distributed by Wire Association on behalf of GSK, on Oct 27, 2022. For more information subscribe and follow us.

Media Assets

Embedded Media

Visit the online press release to interact with the embedded media.

https://wireassociation.eu/newsroom/gsk/releases/en/gsk-provides-update-on-contrast-phase-iii-programme-for-otilimab-in-the-treatment-of-moderate-to-severe-rheumatoid-arthritis-1805

GSK

Newsroom: https://wireassociation.eu/newsroom/gsk
Website: https://www.gsk.com/
Primary Email: corporate.media@gsk.com

Social Media

Facebook - https://www.facebook.com/GSK
Twitter - http://twitter.com/GSK
Youtube - http://www.youtube.com/GSK
Linkedin - http://www.linkedin.com/company/glaxosmithkline
Instagram - https://www.instagram.com/gsk/