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Bioven (Europe) Limited
("Bioven" or the "Company")

FDA GIVES APPROVAL FOR PHASE III TRIAL OF EGF-PTI IN THE USA

London, UK - Bioven, the late-stage biopharmaceutical company focused on cancer, is pleased to announce that it has received regulatory approval from the US Food and Drug Administration (FDA) to enrol patients in the USA in its on-going, international Phase III trial of its novel immunotherapy, EGF-PTI, in non-small cell lung cancer (NSCLC).

Bioven intends to include around five US study centres in the Phase III trial following notification from the FDA that the regulatory review of the Company's Investigational New Drug filing is complete.

The planned lead investigator for the trial in the USA is Dr Ross Camidge, the Director of the Thoracic Oncology Clinical and Clinical Research Programs at the University of Colorado.

Bioven's Phase III trial is seeking to further establish the safety and efficacy of EGF-PTI in inoperable, late-stage NSCLC. A total of 418 patients will participate in the trial, the primary endpoint of which is overall survival. Up to 30 patients are expected to be enrolled in the USA.

EGF-PTI, which was initially developed in Cuba as CIMAvax-EGF, is an immunotherapy that targets the epidermal growth factor/epidermal growth factor receptor (EGF/EGFR) pathway implicated in tumour growth.

EGF-PTI's mode of action is to induce the generation of anti-EGF antibodies, which bind with EGF circulating in the blood to prevent the EGF binding with the EGF receptor. In this way, EGF-PTI neutralises the EGF/EGFR pathway to the uncontrolled cell division of tumour growth.

A biomarker based on the concentration of EGF in the blood is being used to identify patients for recruitment into the trial, whose inclusion criteria also include an assessment of EGFR and other gene mutations. This biomarker was identified by a retrospective analysis of Cuban, Malaysian and European data.

Dr Marianne Nicholson, consultant medical oncologist at Aberdeen Royal Infirmary, Scotland, is the trial's principal investigator.

Further details of the trial are available at the following link: https://clinicaltrials.gov/ct2/show/NCT02187367

Bioven holds exclusive rights to EGF-PTI in territories including Europe, ASEAN and Australasia along with the first right of refusal in the Middle East. Bioven continues in dialogue with Cuba's CIM in connection with US marketing rights.

Steve Drew, Bioven's Chief Executive Officer, said: "We are delighted to have received regulatory approval in the USA to enable us to include US patients in our on-going, international Phase III trial of EGF-PTI in non-small cell lung cancer. EGF-PTI is an exciting immunotherapy which in earlier Cuban studies has shown the potential for a significant overall survival benefit in a devastating disease of high unmet medical need."

Dr Agustin Lage, President of Cuba's CIMAB SA, which licensed rights to EGF-PTI to Bioven, commented: "We are very pleased that our innovative immunotherapy, which was initially developed at the Centre of Molecular Immunology (CIM) in Cuba, is to be trialled in the USA as part of Bioven's international Phase III study. Our clinical studies of this immunotherapy in Cuba have produced compelling clinical data in non-small cell lung cancer and I look forward to our data being replicated in Bioven's study."

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Notes for editors:

About Bioven
Bioven is a late-stage biopharmaceutical company focused on the treatment of cancer. Its strategy is to in-license compounds and develop them through late-stage clinical trials prior to out-licensing to major healthcare or specialty pharma companies.

Bioven's most advanced compound is EGF-PTI, a novel immunotherapy for non-small cell lung cancer (NSCLC), which is currently in an international Phase III trial.

Bioven is a privately held company founded in 2002 in Malaysia and with offices in the UK and Kuala Lumpur. For further information, please visit www.bioven.com.