AMIVAS Ireland Ltd. Receives Authorisation from the Medicines & Healthcare Products Regulatory Agency (MHRA) to Market Artesunate Amivas (artesunate) in U.K. for Initial Treatment of Severe Malaria

Waterford, Ireland – 13 June, 2022 – AMIVAS Ireland Ltd., specialists in treatments for rare and neglected tropical diseases, including severe malaria, announced today the Medicines & Healthcare Products Regulatory Agency (MHRA) has authorised the Company to commercialize its lead product, Artesunate Amivas (artesunate), in the U.K. Artesunate Amivas (artesunate) is intended for initial treatment of severe malaria in adults and children.

The approval was based on the recent recommendation by the Committee for Medicinal Products for Human Use (CHMP) to grant such authorisation.

Artesunate Amivas will be available in Q1 2023 as 110 mg powder and solvent for solution for injection batches and is manufactured to the EMA/MHRA specifications.

Mortality from untreated severe malaria (particularly cerebral malaria) approaches 100 percent.

The U.K. launch of Artesunate Amivas will initiate in the coming months as AMIVAS ramps up production and establishes distribution channels to meet the treatment needs of individuals who present with severe malaria in the U.K. each year. Most of those cases are diagnosed in tourists to Africa and in military personnel deployed to regions where malaria is endemic.

“Receiving MHRA authorisation to bring Artesunate Amivas to the U.K. is extremely gratifying,” said AMIVAS Ireland Ltd., Director, Sean Power. “Physicians caring for patients who have progressed to severe malaria can now be even more confident when treating this very serious medical condition. At AMIVAS, we are pleased to play a role in saving the lives of adults and children in these cases.”

“Receiving safe, efficacious, fast-acting injectable treatment without delay is, quite literally, a life-saving imperative for a patient diagnosed with severe malaria,” said Bryan Smith, M.D., Chief Medical Officer at AMIVAS. “We are proud of our expertise in helping patients. The U.K. launch of Artesunate Amivas will be an exciting milestone to reach because of what it will mean for severe malaria patients and the physicians who care for them.”

Intravenous artesunate has been shown to improve survival in patients with severe malaria in endemic areas and the U.S.A, with particular benefit for patients with high parasitaemia.

Development of Artesunate Amivas in the U.S. took place under U.S. Army Medical Research and Development Command (USAMRDC). Within USAMRDC, the Walter Reed Army Institute of Research and the U.S. Army Medical Materiel Development Activity (USAMMDA) joint collaborative work has provided the Centers for Disease Control and Prevention (CDC) a constant supply of IV artesunate since 2007. USAMMDA established a cooperative research and development agreement with AMIVAS to modernize Artesunate manufacture and register the product with the U.S. Food and Drug Administration.

MHRA authorisation of Artesunate Amivas now meets a key strategic goal to support America's NATO Allies with an approved medical countermeasure for severe malaria.

Where to Find More Information

The product information approved by the MHRA for Artesunate Amivas contains prescribing information for healthcare professionals, a package leaflet for members of the public and details of conditions of the Artesunate Amivas authorisation. An assessment report, with details of the MHRA evaluation of Artesunate Amivas, is available on the MHRA's website. Also available there is an overview of Artesunate Amivas written in lay language, including a description of the medicine's benefits and risks and a description of why MHRA recommended Artesunate Amivas authorisation in the U.K. For more information about Artesunate Amivas, including the Summary of Product Characteristics and Patient Information Leaflet, visit www.AMIVAS.eu or product.mhra.gov.uk/search.

Clinical Studies

The safety and efficacy of IV Artesunate were studied in three trials including the South-East Asian Quinine Artesunate Malaria Trial (SEAQUAMAT) and the African Quinine Artesunate Malaria Trial (AQUAMAT). These two studies examined a total of 6,886 patients and included adults, children and pregnant women. IV Artesunate reduced mortality by 34.7 percent and 22.5 percent compared with the injectable standard of care drug in the SEAQUMAT and AQUAMAT studies respectively. Data were also collected between January 2007 and December 2010 on 102 U.S. patients with severe or complicated malaria who were supplied IV Artesunate under the CDC expanded access protocol. Ninety-two patients received at least one administration of drug at 0, 12, 24 and 48 hours. These U.S. patients included adults, children, pregnant women and older adults. Most were Black or African American, 25 percent were White, 9 percent were Asian. Seven patients died from complications of severe malaria (mortality rate, 6.9 percent). Primary funding source for the data analysis from patients enrolled in the CDC study was the Office of the Surgeon General, Department of the U.S. Army. While no service personnel were actively recruited into any of the clinical trials of IV Artesunate, several service members were offered emergency treatment under the CDC protocol.

To report SUSPECTED ADVERSE REACTIONS, contact AMIVAS Ireland Ltd. at MICC.AMIVAS@4cpharma.com. In other countries, refer to the following telephone number, respectively:

AMIVAS UK: 0800 014 8494

About Malaria and Severe Malaria

Malaria is one of the world's leading killers of people, especially children. Severe malaria, a medical emergency, typically includes neurologic symptoms, severe anaemia, acute renal injury, acute respiratory distress syndrome, or jaundice, as a large number of the patient's red blood cells become infected by a malaria parasite. Uncomplicated falciparum malaria can progress rapidly to severe forms of the disease, especially in people with no or low immunity. Without treatment, severe falciparum malaria is almost always fatal.

Prompt, effective treatment within 24 - 48 hours of the onset of malaria symptoms is necessary.

A rare disease, malaria is not always recognised, diagnosed and treated in timely fashion. Nearly all cases in the U.K. occur in persons who acquire the infection while in a malaria endemic area and who are diagnosed after returning to their home area. Most have no acquired immunity to malaria and are, therefore, at risk of developing severe malaria. A major contributing factor to continued malaria-associated mortality in is delay in initiation of appropriate treatment. Malaria chemoprophylaxis and the use of bed nets and insect repellants help reduce the risk of contracting malaria.

About AMIVAS

AMIVAS is a U.S. joint venture focused on the development, manufacture and commercialization of therapeutic products for the treatment of infectious diseases. Headquartered in Frederick, Maryland, AMIVAS was formed in 2016 expressly for the purpose of bringing treatments to market for rare and neglected tropical diseases. AMIVAS Ireland Ltd. is a wholly owned subsidiary of AMIVAS and is responsible for the U.K. and European markets.

Disclaimer: The views expressed in this release are those of the author and do not necessarily represent the views of the U.S. Army or the Department of Defense (DoD) or U.S. CDC. Discussion of specific pharmaceutical products does not reflect an endorsement of those products.

###

MEDIA CONTACTS:

Sean Power Director, AMIVAS Ireland Ltd. Mark Reid Co-Director, AMIVAS Ireland Ltd. info@AMIVAS.com	Sheila A. Burke Method Health Communications methodhealthcomms@gmail.com +1-484-667-6330