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AMRI receives NIH contract for clinical drug product

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Singapore: Clinical research firm, AMRI, has received a 10-year federal contract award from the National Institutes of Health (NIH) for drug development and manufacturing services.

This NIH/National Institute of Neurological Disorders and Stroke (NINDS) award will support NIH's Drug Manufacturing and Formulation Program (DMFP), which is a component of the Blueprint Neurotherapeutics Network (BPN). AMRI has supported the NIH BPN since 2011, providing chemistry services and discovery technologies. Since 2005 AMRI has collaborated with NINDS in the area of medicinal chemistry on novel treatments for spinal muscular atrophy, a degenerative neuromuscular disease.

The ultimate goal of the DMFP is to support the NINDS and their BPN contributors, drug companies and academic researchers, in the development and manufacture of dosage forms of small molecule drug candidates suitable for administration in preclinical and clinical studies of neurological disease/disorders.

This 10-year contract provides AMRI with funding of up to $37.3 million, based on the number of approved projects and availability of funds, to advance BPN projects having positive results in early stage drug discovery into clinical trials. Services to be provided under this contract will include the manufacture of active pharmaceutical ingredients (API); drug product formulation; analytical testing; and clinical trial supply chain management, including packaging, labeling, storage, and distribution of the completed drug product.

"AMRI was selected for this contract award because of our proven track record on projects with NIH and our demonstrated expertise in drug manufacture and formulation, which is enriched by our integrated pharmaceutical services platform," said William S Marth, President and CEO, AMRI. "Since our initial NIH BPN award in 2011, AMRI has provided discovery chemistry services to NINDS and its private sector BPN members on 15 drug candidate programs, and two of these programs have advanced to the stage where a pre-clinical candidate has been declared, with a third candidate pending.

Under the DMFP, AMRI will be responsible for completing manufacturing, documentation, formulation, fill and finish, packaging, and labeling required for BPN compounds.