Saol Therapeutics Announces FDA Approval of LYVISPAH™ (baclofen) Oral Granules and the Divesture of its Plasma-derived Hyperimmune Portfolio

Saol Therapeutics announces the approval of LYVISPAH™ (baclofen) oral granules

The company also announces the strategic transaction to divest the plasma-derived hyperimmune portfolio to Kamada Ltd. for a total value of up to $160M

ROSWELL, GA US/Dublin, IE/Hamilton, BM Dec. 6, 2021 – Saol Therapeutics today announced that the U.S. Food and Drug Administration (FDA) has approved Saol's LYVISPAH™ (baclofen) oral granules.

LYVISPAH™ (lye-vis'-pah) is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. LYVISPAH™ may also be of some value in patients with spinal cord injuries and other spinal cord diseases. LYVISPAH™ is a strawberry-flavored, dissolvable granular formulation of baclofen and will be available for patients 12 years and above in 5mg, 10mg, and 20mg packets. Unlike other formulations of baclofen, it is approved for administration with or without water, with soft foods and with enteral feeding tubes.

Patients suffering from spasticity may concurrently develop swallowing difficulties. Nearly one million people in the United States are living with multiple sclerosis[1], and the prevalence of spasticity within this patient population has been estimated to be as high as 67%[2]. Additionally, the prevalence of dysphagia in the multiple sclerosis population has been reported to be between 34-43%[3,4], with aspiration pneumonia frequently cited as a contributing factor in deaths of these patients[5].

Dr Michael Saulino, Chair of Physical Medicine and Rehabilitation at Cooper University Hospital commented, "LYVISPAH™ represents an important treatment option for individuals with spasticity who have dysphagia. The bioequivalence between LYVISPAH™ and traditional oral baclofen products should allow for straightforward prescribing by clinicians who manage patients with both clinical problems."

David Penake, CEO of Saol Therapeutics stated, "We are tremendously excited by the approval of LYVISPAH™. Spasticity is a challenging condition to treat, and we have commonly heard that no two patients are alike. Because of this, clinicians stressed to us that there is a need for new formulations designed to benefit their patients who have difficulty swallowing. I'm incredibly proud of the work our team has done to get this approved, and our hope is that this is the first in the line of many new therapies we can bring to market to support health care providers and the patients they treat."

Following this approval, Saol Therapeutics is preparing for a full commercial launch of LYVISPAH™ in 2022.

Additionally, Kamada LTD announced on November 22nd, 2021, the acquisition of our four plasma-derived hyperimmune products for:

- CYTOGAM® (Cytomegalovirus Immune Globulin Intravenous [Human]) (CMV-IGIV) is indicated for the prophylaxis of cytomegalovirus disease associated with the transplantation of the kidney, lung, liver, pancreas, and heart.

- WINRHO® SDF is a Rho(D) Immune Globulin Intravenous (Human) is indicated for use in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage in the treatment of non-splenectomies, for Rho(D)-positive children with chronic or acute immune thrombocytopenia (ITP), adults with chronic ITP, and children and adults with ITP secondary to HIV infection. WinRho SDF is also used for suppression of Rhesus (Rh) Isoimmunization during pregnancy and other obstetric conditions in non-sensitized, Rho(D)-negative women.
- HEPAGAM B® is a hepatitis B Immune Globulin (Human) (HBIg) product indicated to both prevent hepatitis B virus (HBV) recurrence following liver transplantation in hepatitis B surface antigen positive (HBsAg- positive) patients and provide post-exposure prophylaxis.
- VARIZIG® [Varicella Zoster Immune Globulin (Human)] is indicated for post-exposure prophylaxis of varicella (chickenpox) in high-risk patient groups, including immunocompromised children, newborns, and pregnant women. VARIZIG is intended to reduce the severity of chickenpox infections in these patients.

Under the terms of the agreement, Kamada will pay Saol up to $160 million, with a $95 million upfront payment, and up to an additional $50 million in sales milestones during 2022-2034. In addition, Kamada will acquire from Saol existing inventory at an estimated value of approximately $15 million, which will be paid over 10 equal quarterly installments.

“The proceeds from the sale of the hyperimmune products will be invested to expand our commercial infrastructure to launch LYVISPAH™ and further development of our pipeline assets SIL-1002 for Spasticity, SIL-1009 for Pyruvate Dehydrogenase Complex Disorder and SIL-1010 for Chronic Pain associated with Osteoarthritis. The approval of LYVISPAH™ on the same day as the announcement of the transaction highlights our company’s ability to execute on multiple priorities. Moving forward, we have a clear path to growth and continued profitability” concluded Mr. Penake.

About Saol Therapeutics
Saol Therapeutics (pronounced “Sail”) is a privately held, biopharmaceutical company with operations in Roswell, GA, Dublin, Ireland and Hamilton, Bermuda. Saol is focused on commercial and clinical development activity in CNS disorders such as spasticity, pain management, and orphan diseases. Saol is committed to providing and advancing therapeutic options for patients and the physicians treating these populations. For more information, visit www.saolrx.com.

About LYVISPAH™ (baclofen) oral granules
LYVISPAH™ is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. LYVISPAH™ may also be of some value in patient with spinal cord injuries and other spinal cord diseases. LYVISPAH™ is a strawberry-flavored, dissolvable granular formulation of baclofen and will be available for patients 12 years and above in 5mg, 10mg, and 20mg packets.

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IMPORTANT SAFETY INFORMATION

LYVISPAH™ (baclofen) oral granules

Indications and Usage

- LYVISPAH™ (baclofen) oral granules is a muscle relaxant and antispastic that is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.
- LYVISPAH™ may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Limitations of Use

- LYVISPAH™ is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

Contraindications

- LYVISPAH™ is contraindicated in patients with hypersensitivity to baclofen.

Select Warnings and Precautions

- Abrupt discontinuation of baclofen has resulted in serious adverse reactions including death; therefore, reduce the dosage slowly when LYVISPAH™ is discontinued.
- Neonatal withdrawal can occur; gradually reduce the dosage and discontinue LYVISPAH™ before delivery.
- LYVISPAH™ can cause drowsiness and sedation. Patients should avoid the operation of automobiles or other dangerous machinery until they know how the drug affects them. Advise patients that the central nervous system effects of LYVISPAH™ may be additive to those of alcohol and other CNS depressants.
- LYVISPAH™ can cause exacerbation of the following: psychotic disorders, schizophrenia, or confusional states; autonomic dysreflexia; epilepsy. Use with caution in patients with these conditions.
- LYVISPAH™ should be used with caution in patients who have had a stroke.

Adverse Reactions

Serious Adverse Reactions

- Advise patients and caregivers not to discontinue use of LYVISPAH™ without consulting with their healthcare provider because sudden withdrawal of LYVISPAH™ can result in serious complications that include hallucinations, seizures, high fever, confusion, muscle stiffness, multiple organ-system failure, and death. Inform patients that early symptoms of LYVISPAH™ withdrawal may include increased spasticity, itching, and tingling of extremities. Abrupt discontinuation of baclofen, regardless of the cause, has resulted in adverse reactions that include hallucinations, seizures, high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple

organ-system failure, and death. Therefore, reduce the dosage slowly when LYVISPAH™ is discontinued, unless the clinical situation justifies a rapid withdrawal.

Common Adverse Reactions

- The most common adverse reactions (>1%) in patients treated with baclofen for spasticity are drowsiness, dizziness, weakness, nausea, confusion, hypotension, headache, insomnia, constipation, urinary frequency, and fatigue.

Drug Interactions

- LYVISPAH™ (baclofen) oral granules can cause CNS depression when used concomitantly with other CNS depressants and alcohol.

Use in Specific Populations

- There are no adequate data on the developmental risks associated with the use of LYVISPAH™ in pregnant women. LYVISPAH™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Nursing mothers should exercise caution, as oral baclofen has been shown to pass into milk at therapeutic doses.
- Withdrawal symptoms can occur in breastfed infants when maternal administration of LYVISPAH™ is stopped, or when breastfeeding is stopped.
- Safety and effectiveness in pediatric patients below the age of 12 have not been established.
- In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease of other drug therapy.
- Because baclofen is primarily excreted unchanged through the kidneys, LYVISPAH™ should be given with caution to patients with renal impairment, and it may be necessary to reduce the dosage.

For more information, refer to LYVISPAH™ (baclofen) oral granules prescribing information, located at www.LYVISPAH.com/prescribinginformation.

To report SUSPECTED ADVERSE REACTIONS, contact Saol Therapeutics at toll-free phone 1-833 644-4216 or FDA at 1-800- FDA-1088 or www.fda.gov/medwatch.

CYTOGAM® (Cytomegalovirus Immune Globulin Intravenous [Human]) (CMV-IGIV)
Cytogam is contraindicated in individuals with a history of a prior severe reaction associated with the administration of this or other human immunoglobulin preparations. Persons with selective immunoglobulin A deficiency have the potential for developing antibodies to immunoglobulin A and could have anaphylactic reactions to subsequent administration of blood products that contain immunoglobulin A, including Cytogam.

Immune Globulin Intravenous (Human) products have been reported to be associated with renal dysfunction, acute renal failure, osmotic nephrosis, and death. Patients predisposed to acute renal failure include patients with any degree of preexisting renal insufficiency, diabetes mellitus, age greater than 65, volume depletion, sepsis, paraproteinemia, or patients receiving known nephrotoxic drugs. Especially in such patients, IGIV products should be administered at the minimum concentrations available and the minimum rate of infusion practicable. Agents containing sucrose as a stabilizer (Cytogam contains sucrose) have been associated with reports of renal dysfunction given at daily doses of 350 mg/kg or greater.

HEPAGAM B® Hepatitis B Immune Globulin (Human) (HBIg)
Individuals known to have severe, potentially life-threatening reaction to human globulin preparations should not receive HepaGam B® or any other immune globulin (human). Individuals who are deficient in IgA may have the potential to develop IgA antibodies and have severe, potentially life-threatening allergic reactions.
For post-exposure prophylaxis indications, HepaGam B® must be administered intramuscularly only. In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, HepaGam B® should be given only if the expected benefits outweigh the potential risks.
HepaGam B® [Hepatitis B Immune Globulin Intravenous (Human)] is a sterile solution of gamma globulin (IgG) made from human plasma. Products made from human plasma may carry a risk of transmitting infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jacob disease (CJD) agent.

VARIZIG® [Varicella Zoster Immune Globulin (Human)]
In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, only administer VARIZIG if the expected benefits outweigh the potential risks. Thrombotic events may occur following treatment with VARIZIG and other immune globulin products. Individuals known to have severe, potentially life-threatening reactions to human globulin should not receive VARIZIG or any other immune globulin (Human). Individuals who are deficient in IgA may have the potential for developing IgA antibodies and have severe, potentially life-threatening allergic reactions. Products made from human plasma may carry a risk of transmitting infectious agents, e.g. viruses and, theoretically, the Creutzfeldt-Jakob disease agent. The most serious adverse drug reactions observed in clinical trials for all subjects and patients include pyrexia, nausea, chills and vomiting. The most common adverse drug reactions observed in clinical trials for all subjects and patients were injection site pain, headache, chills, fatigue, rash and nausea.

WINRHO® SDF Rho(D) Immune Globulin Intravenous (Human)

WARNING: INTRAVASCULAR HEMOLYSIS (IVH)

Intravascular hemolysis leading to death has been reported in patients treated for ITP with WinRho® SDF.

IVH can lead to clinically compromising anemia and multi-system organ failure including acute respiratory distress syndrome (ARDS).

Serious complications including severe anemia, acute renal insufficiency, renal failure, and disseminated intravascular coagulation (DIC) have also been reported.

Closely monitor patients treated with WinRho® SDF for ITP in a healthcare setting for at least eight hours after administration. Perform a dipstick urinalysis to monitor for hematuria and hemoglobinuria at baseline and 2 hours, 4 hours, and prior to the end of the monitoring period. Alert patients and monitor the signs and symptoms of IVH including back pain, shaking chills, fever, and discolored urine or hematuria. Absence of these signs and/or symptoms of IVH within eight hours does not indicate IVH cannot occur subsequently. If signs and/or symptoms of IVH are present or suspected after WinRho® SDF administration, post-treatment laboratory tests should be performed including plasma hemoglobin, haptoglobin, LDH, and plasma bilirubin (direct and indirect).

For use in the treatment of ITP, do not use WinRho® SDF in:

- Patients who have had known anaphylactic or severe systemic reaction to the administration of human immune globulin products
- IgA deficient patients with antibodies to IgA and a history of hypersensitivity
- Patients with autoimmune hemolytic anemia, with pre-existing hemolysis or at high risk for hemolysis

The liquid formulation of WinRho® SDF contains maltose. Maltose in IGIV products has been shown to give falsely high blood glucose levels in certain types of blood glucose testing systems. Due to the potential for falsely elevated glucose readings, only testing systems that are glucose-specific should be used to test or monitor blood glucose levels in patients receiving WinRho® SDF Liquid.
WinRho® SDF is made from human plasma. It may carry a risk of transmitting infectious agents, e.g. viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

The safety and efficacy of WinRho® SDF have not been evaluated in clinical trials for patients with non-ITP causes of thrombocytopenia or in previously splenectomized patients or in patients who are Rho(D)-negative.