FDA Approves Lilly and Incyte's OLUMIANT® (baricitinib) As First and Only Systemic Medicine for Adults with Severe Alopecia Areata

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INDIANAPOLIS, June 13, 2022 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte (NASDAQ:INCY) announced today that the U.S. Food and Drug Administration (FDA) has approved OLUMIANT® (baricitinib), a once-daily pill, as a first-in-disease systemic treatment for adults with severe alopecia areata (AA), available as 4-mg, 2-mg and 1-mg tablets.[1] The recommended dose is OLUMIANT 2-mg/day, with an increase to 4-mg/day if treatment response is inadequate. For patients with nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss, consider treating with 4-mg/day. Once an adequate response is achieved on 4-mg/day, the dosage is to be decreased to 2-mg/day.[1] OLUMIANT is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.[1]

"People with alopecia areata, dermatologists and other healthcare providers have been looking forward to this day when there is an FDA-approved systemic medicine for this often-devastating disease. Alopecia areata causes unpredictable hair loss that can be patchy or complete, and it affects people of all ages and ethnicities," [2-4] said Brett King, M.D., Ph.D., F.A.A.D., associate professor of dermatology at Yale School of Medicine and lead investigator of the BRAVE-AA program. "I am so happy that adults with severe alopecia areata can now take OLUMIANT, a once-daily pill. The results of clinical trials are remarkable, as one in five adults taking OLUMIANT 2-mg/day and one in three taking OLUMIANT 4-mg/day achieved significant hair regrowth resulting in 80% or more scalp coverage, and eyebrow and eyelash improvements were also achieved for patients taking OLUMIANT 4-mg/day with substantial eyebrow or eyelash hair loss."[1]

The approval was based on Lilly's BRAVE-AA1 and BRAVE-AA2 trials, the largest Phase 3 AA clinical trial program completed to date,[5-7] evaluating the efficacy and safety of OLUMIANT in 1,200 adult patients with severe AA (≥50% scalp hair loss as defined by a Severity of Alopecia Tool (SALT) score ≥50).[1] Across the studies at 36 weeks, 17-22% of patients taking OLUMIANT 2-mg/day and 32-35% of patients taking OLUMIANT 4-mg/day achieved 80% or more scalp hair coverage, compared to 3-5% taking placebo.[1] Additionally, 11-13% of patients taking OLUMIANT 2-mg/day and 24-26% of patients taking OLUMIANT 4-mg/day achieved 90% or more hair coverage, compared to 1-4% of patients taking placebo; results for OLUMIANT 2-mg/day were not statistically significant under the multiplicity control plan for BRAVE-AA2.[1]

Among patients with substantial eyebrow and eyelash hair loss at baseline, improvements in eyebrow and eyelash coverage were seen for patients taking OLUMIANT 4-mg daily at 36 weeks.[1]

The BRAVE-AA clinical program evaluated the safety profile of OLUMIANT.[1] Few patients discontinued treatment due to adverse events (average of 2.2% across both studies) in the 36-week placebo-controlled period and the majority of treatment-emergent adverse events were mild or moderate in severity.[8] The most commonly reported adverse reactions (≥1%) were upper respiratory tract infections, headache, acne, high cholesterol levels, increases in blood markers related to the muscle, urinary tract infections, elevated liver enzyme levels, inflammation of hair follicles, fatigue, lower respiratory tract infections, nausea, genital yeast infection, low red blood cell counts, low white blood cell counts, abdominal pain, shingles and weight increase.[1] The U.S. FDA-approved labeling for OLUMIANT includes a boxed warning for risk of serious infections, mortality, malignancy, major adverse cardiovascular events (MACE) and thrombosis.[1] See below for full Important Safety Information.

"Today marks a milestone with the first-ever FDA-approved systemic treatment for alopecia areata patients, who face significant challenges every day including limited public knowledge about the disease, a lack of treatment options and social stigma,"[9] said Nicole Friedland, president and chief executive officer, National Alopecia Areata Foundation (NAAF). "The approval of OLUMIANT can spark hope for many patients and encourage new treatment conversations with their doctors. NAAF wants more choices for our patient community and with the approval of OLUMIANT, there are now new treatment expectations being established in alopecia areata care."

Lilly is committed to ensuring patients have access to much-needed medicines and is working with insurers to do so. Through the OLUMIANT Together™ support program, Lilly offers a savings card for eligible commercially insured patients* to help with out-of-pocket costs where they pay as little as $5/month if covered by their insurance provider or $25/month if not covered by their plan. The savings card is available at specialty pharmacies, and in the coming days will be available for download on OLUMIANT.com.

"There is a significant unmet medical need for people with alopecia areata given there has never been an FDA-approved systemic medicine. In fact, a study published in 2017 of 1,083 people with AA showed that nearly 80 percent were unsatisfied with their treatment options,"[10] said Patrik Jonsson, Lilly senior vice president, president of Lilly Immunology and Lilly USA, and chief customer officer. "Our mission is to make life better for people living with debilitating immune-mediated diseases. OLUMIANT's approval is a historic moment, and we're delighted about what it can mean for adults with severe alopecia areata."

Learn more about OLUMIANT; view the 2-mg and 4-mg product photos and brand logo.

OLUMIANT is a once-daily, oral JAK inhibitor discovered by Incyte and licensed to Lilly and is available through specialty pharmacies nationwide. Lilly also expects regulatory decisions for OLUMIANT in AA in the European Union and Japan in 2022.

About BRAVE-AA1 and BRAVE-AA2
In these double-blind, placebo-controlled Phase 3 trials, 1,200 patients with severe AA were randomized to receive once-daily OLUMIANT 2-mg, OLUMIANT 4-mg or placebo.

- The primary endpoint was the proportion of patients achieving SALT ≤20 (i.e., 80% or more scalp hair coverage) at Week 36.[1] Across both studies, 17-22% of patients taking OLUMIANT 2-mg/day (BRAVE-AA1=22% [n=40/184]; BRAVE-AA2=17% [n=27/156]) and 32-35% of patients treated with OLUMIANT 4-mg/day (BRAVE-AA1=35% [n=99/281]; BRAVE-AA2=32% [n=76/234]) achieved 80% or more scalp hair coverage, compared to 5% (n=10/189) and 3% (n=4/156) of patients taking placebo in BRAVE-AA1 and BRAVE-AA2, respectively (p≤0.001 for all comparisons to placebo).
- Additionally, 11-13% of patients taking OLUMIANT 2-mg/day (BRAVE-AA1=13% [n=23/184]; BRAVE-AA2=11% [n=17/156]) and 24-26% of patients taking OLUMIANT 4-mg/day (BRAVE-AA1=26% [n=73/281]; BRAVE-AA2=24% [n=55/234]) achieved 90% or more hair coverage, compared to 4% (n=7/189) and 1% (n=1/156) of patients taking placebo in BRAVE-AA1 and BRAVE-AA2, respectively (p<=0.001 for OLUMIANT 4-mg/day comparisons to placebo; p<=0.01 for OLUMIANT 2-mg/day comparison to placebo in BRAVE-AA1).[1,8] SALT 10 (90% hair coverage) results for OLUMIANT 2-mg/day were not statistically significant under the multiplicity control plan for BRAVE-AA2.[8]

Indications and Usage for OLUMIANT (baricitinib) tablets (in the United States)

OLUMIANT is indicated for the treatment of adult patients with severe alopecia areata.

Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

OLUMIANT is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) blockers.

Limitations of Use: Not recommended for use in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.

OLUMIANT is indicated for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

IMPORTANT SAFETY INFORMATION FOR OLUMIANT (baricitinib) tablets

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

SERIOUS INFECTIONS

Patients treated with Olumiant are at risk for developing serious infections that may lead to hospitalization or death. Most patients with rheumatoid arthritis (RA) who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. If a serious infection develops, interrupt Olumiant until the infection is controlled. Reported infections include:

- **Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Olumiant should not be given to patients with active tuberculosis. Test patients, except those with COVID-19, for latent TB before initiating Olumiant and during therapy. If positive, start treatment for latent infection prior to Olumiant use.**
- **Invasive fungal infections, including candidiasis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, and other infections due to opportunistic pathogens.**

Carefully consider the risks and benefits of Olumiant prior to initiating therapy in patients with chronic or recurrent infection.

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with Olumiant including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

The most common serious infections reported with Olumiant included pneumonia, herpes zoster, and urinary tract infection. Among opportunistic infections, tuberculosis, multidermatomal herpes zoster, esophageal candidiasis, pneumocystosis, acute histoplasmosis, cryptococcosis, cytomegalovirus, and BK virus were reported with Olumiant. Some patients have presented with disseminated rather than localized disease, and were often taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Avoid use of Olumiant in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating Olumiant in patients: with chronic or recurrent infection; who have been exposed to TB; with a history of a serious or an opportunistic infection; who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or with underlying conditions that may predispose them to infection.

The risks and benefits of treatment with Olumiant in COVID-19 patients with other concurrent infections should be considered.

Consider anti-TB therapy prior to initiation of Olumiant in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but who have risk factors for TB infection.

Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies with Olumiant. If a patient develops herpes zoster, interrupt Olumiant treatment until the episode resolves. The impact of Olumiant on chronic viral hepatitis reactivation is unknown. Screen for viral hepatitis in accordance with clinical guidelines before initiating Olumiant.

MORTALITY

In a large, randomized, postmarketing safety study in RA patients 50 years of age and older with at least one cardiovascular risk factor

comparing another Janus kinase (JAK) inhibitor to tumor necrosis factor (TNF) blockers, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant.

MALIGNANCIES

Lymphoma and other malignancies have been observed in patients treated with Olumiant. In RA patients treated with another JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer [NMSC]) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. A higher rate of lymphomas was observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. A higher rate of lung cancers and an additional increased risk of overall malignancies were observed in current or past smokers treated with the JAK inhibitor compared to those treated with TNF blockers.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients with a known malignancy (other than successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers.

NMSCs have been reported in patients treated with Olumiant. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction [MI], and stroke) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue Olumiant in patients that have experienced a myocardial infarction or stroke.

Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Olumiant, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Inform patients about the symptoms of serious cardiovascular events and the steps to take if they occur.

THROMBOSIS

Thrombosis, including deep venous thrombosis (DVT) and pulmonary embolism (PE), has been observed at an increased incidence in patients treated with Olumiant compared to placebo. In addition, there were cases of arterial thrombosis. Many of these adverse events were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid Olumiant in patients at risk. Discontinue Olumiant and promptly evaluate patients with symptoms of thrombosis.

HYPERSENSITIVITY

Reactions such as angioedema, urticaria, and rash that may reflect drug hypersensitivity have been observed in patients receiving Olumiant, including serious reactions. If a serious hypersensitivity reaction occurs, promptly discontinue Olumiant while evaluating the potential causes of the reaction.

GASTROINTESTINAL PERFORATIONS

Gastrointestinal perforations have been reported in Olumiant clinical studies. Monitor Olumiant-treated patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis). Promptly evaluate patients who present with new onset abdominal symptoms for early identification of gastrointestinal perforation.

LABORATORY ABNORMALITIES

Neutropenia – Olumiant treatment was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] <1000 cells/mm^3) compared to placebo. Evaluate at baseline and thereafter according to routine patient management.

In patients with RA or alopecia areata (AA), avoid initiation or interrupt Olumiant treatment in patients with an ANC <1000 cells/mm^3. In patients with COVID-19, avoid initiation or interrupt Olumiant treatment in patients with an ANC <500 cells/mm^3.

Lymphopenia – Absolute lymphocyte count (ALC) <500 cells/mm^3 were reported in Olumiant clinical trials. Lymphocyte counts less than the lower limit of normal were associated with infection in patients treated with Olumiant, but not placebo. Evaluate at baseline and thereafter according to routine patient management.

In patients with RA or AA, avoid initiation or interrupt Olumiant treatment in patients with an ALC <500 cells/mm^3. In patients with COVID-19, avoid initiation or interrupt Olumiant treatment in patients with an ALC <200 cells/mm^3.

Anemia – Decreases in hemoglobin levels to <8 g/dL were reported in Olumiant clinical trials. Evaluate at baseline and thereafter according to routine patient management.

In patients with RA or AA, avoid initiation or interrupt Olumiant treatment in patients with hemoglobin <8 g/dL. In patients with COVID-19, there is limited information regarding use of Olumiant in patients with hemoglobin less than 8 g/dL.

Liver Enzyme Elevations – Olumiant treatment was associated with increased incidence of liver enzyme elevation compared to placebo. Increases of alanine transaminase (ALT) ≥5x upper limit of normal (ULN) and increases of aspartate transaminase (AST) ≥10x ULN were observed in patients in Olumiant clinical trials.

Evaluate at baseline and thereafter according to routine patient management. Promptly investigate the cause of liver enzyme elevation to identify potential cases of drug-induced liver injury. If increases in ALT or AST are observed and drug-induced liver injury is suspected, interrupt Olumiant until

this diagnosis is excluded.

Lipid Elevations – Treatment with Olumiant was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol. Assess lipid parameters approximately 12 weeks following Olumiant initiation in patients with RA or AA. Manage patients according to clinical guidelines for the management of hyperlipidemia.

VACCINATIONS

Avoid use of live vaccines with Olumiant. Update immunizations in patients with RA or AA prior to initiating Olumiant therapy in agreement with current immunization guidelines.

ADVERSE REACTIONS

In RA trials, the most common adverse reactions (≥1%) reported with Olumiant were: upper respiratory tract infections, nausea, herpes simplex, and herpes zoster.

In COVID-19 trials, the most common adverse reactions (≥1%) reported with Olumiant were: ALT ≥3x ULN, AST ≥3x ULN, thrombocytosis (platelets >600,000 cells/mm^3), creatine phosphokinase >5x ULN, neutropenia (ANC <1000 cells/mm^3), DVT, PE, and urinary tract infection.

In AA trials, the most common adverse reactions (≥1%) reported with Olumiant were: upper respiratory tract infections, headache, acne, hyperlipidemia, creatine phosphokinase increase, urinary tract infections, liver enzyme elevations, folliculitis, fatigue, lower respiratory tract infections, nausea, genital Candida infections, anemia, neutropenia, abdominal pain, herpes zoster, and weight increase.

PREGNANCY AND LACTATION

Based on animal studies, Olumiant may cause fetal harm when administered during pregnancy. Advise pregnant women and women of reproductive potential of the potential risk to a fetus. Consider pregnancy planning and prevention for women of reproductive potential. Advise women not to breastfeed during treatment with Olumiant and for 4 days after the last dose.

HEPATIC AND RENAL IMPAIRMENT

Olumiant is not recommended in patients with RA or AA and severe hepatic impairment or severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min/1.73m^2).

Olumiant should only be used in patients with COVID-19 and severe hepatic impairment if the potential benefit outweighs the potential risk. Olumiant is not recommended in patients with COVID-19 who are on dialysis, have end-stage renal disease, or with eGFR <15 mL/min/1.73m^2.

Please click to access full Prescribing Information, including Boxed Warning about Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis, and Medication Guide.

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***Savings Card Terms and Conditions**
Offer good until 12/31/2024 or up to 36 months from patient qualification into the program, whichever comes first. Patients must first use their card by 12/31/2022. Patients must have coverage for Olumiant through their commercial drug insurance to pay as little as $5 for a 30-day supply of Olumiant. Offer subject to a monthly cap and a separate annual cap. Patients must have commercial drug insurance and prescription consistent with FDA-approved product labeling to pay as little as $25 for a 30-day supply of Olumiant. Participation in the $25 program requires submission of a prior authorization (PA). If coverage is denied, an appeal must be submitted prior to the 5th month fill. A new PA and appeal or medical exception (ME) must be submitted every 12 months or as required by Lilly to verify coverage status and potential eligibility for the $5 program. Monthly and annual caps are set at Lilly's absolute discretion and may be changed by Lilly with or without notice. Patient is responsible for any applicable taxes, fees, or amounts exceeding monthly or annual caps. **This offer is invalid for patients without commercial drug insurance or whose prescription claims for Olumiant are eligible to be reimbursed, in whole or in part, by any governmental program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any state patient or pharmaceutical assistance program.** Offer void where prohibited by law and subject to change or discontinue without notice. Card activation is required. Subject to additional terms and conditions, which can be found at olumiant.com/olumiant-together.

About OLUMIANT®
OLUMIANT, a once-daily, oral JAK inhibitor, was discovered by Incyte and licensed to Lilly. It is approved in the U.S. and more than 75 countries as a treatment for adults with moderate to severe rheumatoid arthritis. FDA approval was granted for OLUMIANT for the treatment of certain hospitalized adult patients with COVD-19 in May 2022. Marketing authorization for OLUMIANT in COVID-19 has been granted in six other countries including Japan and Switzerland. The U.S. FDA-approved labeling for OLUMIANT includes a Boxed Warning for Serious Infections, Mortality, Malignancy, Major Adverse Cardiovascular Events, and Thrombosis. See the full Prescribing Information here.

In December 2009, Lilly and Incyte announced an exclusive worldwide license and collaboration agreement for the development and commercialization of OLUMIANT and certain follow-on compounds for patients with inflammatory and autoimmune diseases.

About Lilly
Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 47 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/newsroom or follow us on Facebook, Instagram, Twitter and LinkedIn. P-LLY

About Incyte
Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit Incyte.com and follow @Incyte.

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Lilly Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about OLUMIANT (baricitinib) as a treatment for alopecia areata and reflects Lilly's and Incyte's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there can be no guarantee that planned or ongoing studies will be completed as planned, that future study results will be consistent with the results to date, and that OLUMIANT will receive additional regulatory approvals, or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's and Incyte's most recent respective Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly and Incyte undertake no duty to update forward-looking statements to reflect events after the date of this release.

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