Testing the Addition of Ipatasertib to Usual Chemotherapy and Radiation for Head and Neck Cancer

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Patients must have pathologically confirmed HNSCC (including tumors of the oropharynx, hypopharynx, larynx, oral cavity, nasal cavity, maxillary and other paranasal sinuses, and unknown primary of the head and neck), with measurable disease as per RECIST 1.1 * Oropharyngeal and unknown primary squamous cell cancers must test for human papilloma virus (HPV), for example by p16 immunohistochemistry (IHC), in situ hybridization (ISH), or polymerase chain reaction (PCR). HPV testing is not required for other HNSCC primary tumor sites * For the dose escalation phase only (not the expansion phase), patients with p16-positive tumors are eligible if clinical stage III (cT4 or cN3, M0) according to the American Joint Committee on Cancer (AJCC)/TNM Staging System, 8th edition (Ed.) * For both the dose escalation and expansion phases, patients with p16-negative (or not tested) tumors are eligible if clinical stage III-IVB (locally advanced but non-metastatic) according to the AJCC/TNM Staging System, 8th Ed. * Must be candidate for concurrent, definitive cisplatin and radiation therapy as judged by the treating physician * Able to swallow tablets at the time of enrollment * Age \>= 18 years. Because no dosing or adverse event data are currently available on the use of ipatasertib in combination with chemoradiation in patients \< 18 years of age, children are excluded from this study * Eastern Cooperative Oncology Group (ECOG) performance status 0-1 * Life expectancy of greater than 3 months * Absolute neutrophil count \>= 3000/mcL * Hemoglobin \>= 10 g/dL * Platelets \>= 150,000/mcL * Serum albumin \>= 3 g/dL * Total bilirubin =\< 1.5 x institutional upper limit of normal (ULN) * Aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase \[SGOT\])/alanine aminotransferase (ALT) (serum glutamate pyruvate transaminase \[SGPT\]) =\< 2.5 x institutional ULN / 2 x institutional ULN * Alkaline phosphatase (ALP) =\< 2.0 x institutional ULN * Partial thromboplastin time (PTT) (or activated \[a\]PTT) and international normalized ratio (INR) =\< 1.5 institutional ULN (except for patients receiving anticoagulation therapy) * Creatinine clearance (CLcr) \> 60 mL/min * For this calculation, use the Cockroft-Gault formula * Fasting glucose =\< 150 mg/dL (8.3 mmol/L) and (when indicated) glycosylated hemoglobin (HbA1c) =\< 7.5% (58 mmol/mol) * Human immunodeficiency virus (HIV)-infected patients are eligible if on effective anti-retroviral therapy with undetectable viral load within 6 months * Patients with past hepatitis B virus (HBV) infection or resolved HBV infection (defined as having a negative hepatitis B virus surface antigen \[HBsAg\] test and a positive hepatitis B core antibody \[HBcAb\] test, accompanied by a negative HBV deoxyribonucleic acid \[DNA\] test) are eligible. Patients with chronic HBV infection are eligible if the HBV viral load is undetectable on suppressive therapy, if indicated. Patients undergoing current treatment with anti-viral therapy for HBV are ineligible * Patients with a history of hepatitis C virus (HCV) infection are eligible only if polymerase chain reaction (PCR) is negative for HCV ribonucleic acid (RNA). Patients with HCV infection who are currently on treatment are eligible if they have an undetectable HCV viral load * Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial * The effects of ipatasertib on the developing human fetus are unknown. For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods with a failure rate of \< 1% per year during the treatment period and for at least 28 days after the last dose of ipatasertib and agreement to refrain from donating eggs during this same period. For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures, and agreement to refrain from donating sperm during the treatment period and for 28 days after the last dose of ipatasertib * Ability to understand and the willingness to sign a written informed consent document * For the expansion cohort only, patients must agree to undergo mandatory on-treatment biopsies, and have tumors amenable to on-treatment biopsies. This is not applicable to the dose escalation cohort where no on-treatment biopsies are obtained

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Exclusion Criteria:

* Primary tumor of nasopharynx, salivary, thyroid or parathyroid glands, or skin * Distant metastases from the current HNSCC * Prior treatment (e.g., chemotherapy, radiation, or definitive surgery) for the current locally advanced HNSCC is not permitted. Biopsies, including those performed under anesthesia, are not considered surgery. Patients who underwent prior definitive surgery alone for an early stage (T1-2N0) HNSCC which has now recurred with stage III-IVB disease at least 3 months after the initial surgery are eligible * For patients with a prior history of another malignancy, no prior chemotherapy or radiation may have been administered within 6 weeks prior to study entry. Among patients who received prior radiation to the head and neck or adjacent anatomical site for another malignancy, there may be no overlap with current area to be irradiated * Current use of any other investigational agents * History of allergic reactions attributed to compounds of similar chemical or biologic composition to ipatasertib or other agents used in study * Treatment with strong inhibitors or inducers of CYP3A4 or P-glycoprotein within 2 weeks or 5 drug-elimination half-lives, whichever is longer, prior to initiation of study drug. Because the lists of these agents are constantly changing, it is important to regularly consult a frequently-updated medical reference. As part of the enrollment/informed consent procedures, the patient will be counseled on the risk of interactions with other agents, and what to do if new medications need to be prescribed or if the patient is considering a new over-the-counter medicine or herbal product * Patients with uncontrolled intercurrent illness, including active infection * Pregnant women are excluded from this study because ipatasertib is an oral AKT inhibitor with the potential for teratogenic or abortifacient effects. Because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with ipatasertib, breastfeeding should be discontinued if the mother is treated with ipatasertib. These potential risks may also apply to other agents used in this study * Patients with type I or type II diabetes mellitus requiring insulin at study entry. Patients with non-insulin dependent type II diabetes mellitus are eligible, as are patients who are on a stable dose of oral diabetes medication \>= 4 weeks prior to initiation of study treatment. Patients with a history of diabetes mellitus, an abnormal fasting glucose level, or other signs or symptoms indicating diabetes mellitus, must meet the laboratory eligibility criteria for fasting blood glucose and hemoglobin A1c * History of or active inflammatory bowel disease (e.g., Crohn's disease and ulcerative colitis) or active bowel inflammation (e.g., diverticulitis) * History of malabsorption syndrome or other condition that would interfere with enteral absorption or results in the inability or unwillingness to swallow pills * Lung disease: pneumonitis, interstitial lung disease, idiopathic pulmonary fibrosis, cystic fibrosis, aspergillosis, active tuberculosis, or history of opportunistic infections (pneumocystis pneumonia or cytomegalovirus pneumonia) * Known clinically significant history of liver disease consistent with Child Pugh Class B or C, including active viral or other hepatitis (e.g., positive for hepatitis B surface antigen \[HBsAg\] or hepatitis C virus \[HCV\] antibody at screening), or cirrhosis * Grade \>= 2 uncontrolled or untreated hypercholesterolemia (cholesterol \> 300 mg/dL or \> 7.75 mmol/L) or hypertriglyceridemia (triglycerides \> 300 mg/dL or \> 3.42 mmol/L)

Conditions & Interventions

Interventions:

PROCEDURE: Biopsy Procedure, PROCEDURE: Biospecimen Collection, DRUG: Cisplatin, PROCEDURE: Computed Tomography, DRUG: Ipatasertib, PROCEDURE: Magnetic Resonance Imaging, PROCEDURE: Positron Emission Tomography, RADIATION: Radiation Therapy

Conditions:

Clinical Stage III HPV-Mediated (p16-Positive) Oropharyngeal Carcinoma AJCC v8, Head and Neck Carcinoma of Unknown Primary, Locally Advanced Head and Neck Squamous Cell Carcinoma, Locally Advanced Hypopharyngeal Squamous Cell Carcinoma, Locally Advanced Laryngeal Squamous Cell Carcinoma, Locally Advanced Nasal Cavity Squamous Cell Carcinoma, Locally Advanced Oral Cavity Squamous Cell Carcinoma, Locally Advanced Oropharyngeal Squamous Cell Carcinoma

Nasal Cavity Squamous Cell Carcinoma, Locally Advanced Oral Cavity Squamous Cell Carcinoma, Locally Advanced Oropharyngeal Squamous Cell Carcinoma, Locally Advanced Paranasal Sinus Squamous Cell Carcinoma, Locally Advanced Sinonasal Squamous Cell Carcinoma, Maxillary Sinus Squamous Cell Carcinoma, Stage III Hypopharyngeal Carcinoma AJCC v8, Stage III Laryngeal Cancer AJCC v8, Stage III Lip and Oral Cavity Cancer AJCC v8, Stage III Oropharyngeal (p16-Negative) Carcinoma AJCC v8, Stage III Sinonasal Cancer AJCC v8, Stage IVA Hypopharyngeal Carcinoma AJCC v8, Stage IVA Laryngeal Cancer AJCC v8, Stage IVA Lip and Oral Cavity Cancer AJCC v8, Stage IVA Oropharyngeal (p16-Negative) Carcinoma AJCC v8, Stage IVA Sinonasal Cancer AJCC v8, Stage IVB Hypopharyngeal Carcinoma AJCC v8, Stage IVB Laryngeal Cancer AJCC v8, Stage IVB Lip and Oral Cavity Cancer AJCC v8, Stage IVB Oropharyngeal (p16-Negative) Carcinoma AJCC v8, Stage IVB Sinonasal Cancer AJCC v8

More Information

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