Summary: Non Interventional Study (NIS) with sonidegib

Non-interventional, multi-national, multi-center post-authorization safety study (PASS) to assess the long-term safety and tolerability of **O**domzo® (sonidegib) administered in patients with locally advanced basal cell carcinoma (laBCC) - **NISSO**

Study design

This is a non-interventional, multinational, multi-center post-authorization safety study, to further assess the safety of sonidegib administered in routine clinical practice in patients with laBCC who are not amendable to curative surgery or radiation therapy.

This study is observational in nature and does not impose a therapy protocol, diagnostic/therapeutic interventions or a specific visit schedule. Data will be collected at enrollment and at routine visits, according to the physician's practice

For this study, each enrolled patient will be observed for 3 years after enrollment. Data will be collected at screening/enrollment and at routine visits, according to the physician's practice; data should be collected at least two times per year for the period of 3 years from enrollment.

The study will collect safety data including concurrent medications, adverse events, and laboratory data during the period on treatment (plus an additional 30 day safety follow-up) and specific safety data after treatment discontinuation, including data on second primary malignancy, death, new antineoplastic treatments during 3 years following enrollment

Population

Patients aged 18 years or older with a diagnosis of laBCC and who are treated with sonidegib 200 mg taken orally once daily.

Inclusion criteria

Patients eligible for inclusion in this study have to meet **all** of the following criteria:

1. Written informed consent or equivalent document (e.g., written information) as per country regulation
2. Patients aged 18 years or older with a diagnosis of laBCC who are not amenable to curative surgery or radiation therapy
3. Patients must be treated with sonidegib 200 mg orally taken once daily (dose modifications according to the approved local country prescribing information are permitted)
4. Sonidegib treatment must be started either at the first visit for this study or prior to study entry.

Exclusion criteria

1. Patients treated with any hedgehog pathway inhibitor besides sonidegib within 3 months prior to study entry
2. Patients currently enrolled in an interventional clinical trial
3. Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the Summary of Product Characteristics (SmPC)
4. Pregnancy and breast-feeding
5. Women of childbearing potential who do not comply with the Odomzo Pregnancy Prevention Programme (as defined in sections 4.4 and 4.6 of the approved SmPC).
6. Male patients who are unable to follow or comply with the required contraception measure