Idhifa access in Saudi Arabia: the SFDA Personal Importation Program

How patients in the Kingdom of Saudi Arabia access Idhifa (enasidenib) for IDH2-mutated relapsed or refractory acute myeloid leukemia.

Last reviewed 2026-05-12 by Reserve Meds clinical and regulatory team.

1. Quick orientation

Idhifa is the brand name for enasidenib, an orally bioavailable small-molecule selective inhibitor of mutant isocitrate dehydrogenase-2 (IDH2). The US Food and Drug Administration granted regular approval to Idhifa on August 1, 2017 for adult patients with relapsed or refractory acute myeloid leukemia (AML) carrying an IDH2 mutation, as detected by an FDA-approved companion diagnostic. The approval was the first FDA approval of any therapy specifically for IDH2-mutated AML and was issued together with the approval of the Abbott RealTime IDH2 Assay as the companion diagnostic. Bristol Myers Squibb (BMS) holds the US new drug application following the November 2019 acquisition of Celgene, the original co-developer with Agios Pharmaceuticals. In the Kingdom of Saudi Arabia, Idhifa is not locally registered with the Saudi Food and Drug Authority (SFDA), and Servier, which acquired the ex-US rights via the 2020 Agios oncology business purchase, has not refiled centrally in the region. Saudi patients whose hematologist has confirmed IDH2 mutation status and prescribed Idhifa reach the medicine through the SFDA Personal Importation Program (PIP). Reserved for you.

2. Why Saudi Arabia patients need Idhifa via the named-patient pathway

The Kingdom operates one of the most mature pharmaceutical regulatory frameworks in the Gulf Cooperation Council. SFDA maintains the national drug registration list and has run a well-developed named-patient framework for over a decade. Three patterns of access gap appear in the Kingdom: a drug is registered with SFDA but not stocked at the treating hospital; a drug is registered for one indication but the physician is prescribing it for a different FDA-approved indication that has not been added to the local label; or the drug is FDA-approved but has never been submitted for SFDA registration.

Idhifa sits squarely in the third pattern. The original EMA marketing authorisation application was withdrawn by Celgene in early 2020, there is no UK MHRA separate authorisation, no Health Canada or PMDA Japan approval on the public registries, and no current local registration in the Kingdom, the UAE, Egypt, or India. There is no local stock to dispense from a domestic pharmacy.

The clinical setting reinforces the named-patient route. Idhifa is biomarker-driven. Patients reach Idhifa only after IDH2 mutation testing confirms eligibility, which means the prescribing hematologist already knows the patient cannot use a substitute IDH1 inhibitor, BCL-2 inhibitor, or hypomethylating agent in place of enasidenib. Substitution is not a clinical option once the IDH2 mutation is identified. IDH2 mutations occur in roughly 8 to 19 percent of AML cases depending on cohort, and only a subset are in the relapsed or refractory setting, so the addressable Saudi patient population in any one year sits in the dozens rather than the hundreds. The economics structurally favor the PIP route for these patients, and the SFDA framework explicitly contemplates oncology, rare disease, and hematology indications of this kind.

3. The SFDA Personal Importation Program for Idhifa

The SFDA Personal Importation Program allows a Kingdom-licensed physician to request import of a specific medicine for a specific named patient when the medicine is approved by a recognised reference authority (typically the US FDA, EMA, MHRA, PMDA Japan, or Health Canada) and a clinically equivalent locally registered alternative is not suitable.

Applications are filed through the dispensing institution's import pharmacy and reviewed by SFDA's Drug Sector. SFDA increasingly routes named-patient activity through its Ghad digital platform alongside the agency's English portal at sfda.gov.sa.

A complete PIP application for Idhifa includes the clinical justification letter from the treating hematologist (diagnosis with ICD-10 coding, disease severity and trajectory, prior therapies attempted with outcomes, why a locally registered alternative is not suitable, and the specific drug, dose, and duration requested); the treating physician's licensing verification through the Saudi Commission for Health Specialties (SCFHS) in hematology or medical oncology; the patient identifier in the format SFDA requires for the named-patient case file; full product details (Idhifa, enasidenib, BMS, 50 mg or 100 mg film-coated tablets, 30-count bottle, requested quantity, lot, and expiry); the destination dispensing facility license; and a chain-of-custody plan from the US point of release through international transit to the receiving Saudi pharmacy.

The clinical-justification angle for Idhifa turns on companion-diagnostic documentation. The hematologist documents the IDH2 mutation testing platform (Abbott RealTime IDH2 Assay or a CLIA-certified IDH2 next-generation sequencing panel), the specific mutation variant (R140 or R172 codon), the date of pathology, the relapsed or refractory disease status, prior induction or salvage regimens and their outcomes, and the planned dosing of 100 mg orally once daily continuously with a minimum six-month trial built into the plan because the differentiation mechanism produces delayed responses (median time to first response approximately 1.9 months and to best response approximately 3.7 months from the Phase 1/2 AG221-C-001 program). Approval timelines for routine SFDA cases run 10 to 21 business days. Complex first-import cases (novel mechanism, ultra-rare population, first-time importer at the institution) can extend to 6 to 10 weeks.

4. Where Idhifa gets dispensed in Saudi Arabia

Idhifa is a room-temperature oral tablet supplied in 50 mg and 100 mg strengths in 30-count bottles, with no refrigeration, reconstitution, or infusion infrastructure required. The dispensing requirement is therefore an SFDA-licensed hospital outpatient pharmacy or specialty import pharmacy aligned with a hematology or medical-oncology service capable of monitoring for the boxed warning on differentiation syndrome.

Kingdom institutions that handle named-patient hematology imports as routine workflow and have in-house adult hematology programs include King Faisal Specialist Hospital and Research Centre (KFSH&RC) in Riyadh, Jeddah, and Madinah, with strong oncology, bone marrow transplant, and rare-disease capability and an experienced in-house import pharmacy; King Abdulaziz Medical City (KAMC) and the Ministry of National Guard Health Affairs (MNGHA) network in Riyadh and Jeddah; King Saud University Medical City (KSUMC); Dr. Sulaiman Al Habib Medical Group (HMG), the largest private hospital network in the Kingdom with multiple Riyadh, Jeddah, and Eastern Province facilities and routine PIP activity; Saudi German Hospital; Dr. Soliman Fakeeh Hospital in Jeddah; and Dallah Hospital in Riyadh. For hematologists at smaller hospitals without an internal import pharmacy, the practical route is to partner with an SFDA-licensed specialty importer based in Riyadh or Jeddah, which handles the SFDA filing, chain-of-custody documentation, and customs clearance while the institution's hematology service retains clinical responsibility.

5. Real cost picture for Idhifa in Saudi Arabia

The Saudi riyal is pegged at approximately 3.75 SAR to 1 USD, which makes the dollar-denominated US wholesale acquisition cost the principal driver of the case economics. Three line items frame the cost.

First, drug cost. The BMS-published US wholesale acquisition cost is approximately USD 36,034 per 30-day supply at either the 50 mg or 100 mg once-daily dose, which is roughly SAR 135,000 per 30-day bottle. A 12-month course at full label dose corresponds to approximately USD 420,000 to USD 440,000 at US WAC (roughly SAR 1,575,000 to SAR 1,650,000) before any rebates, copay assistance, or 340B pricing. BMS Access Support copay assistance and the BMS Patient Assistance Foundation are explicitly US-only and do not extend to patients outside the United States.

Second, international logistics. Idhifa is room-temperature stable with permitted excursions between 15 and 30 degrees Celsius, which is the most permissive class of handling. International logistics for an ambient shipment to the Kingdom

typically runs SAR 1,500 to SAR 3,750 (approximately USD 400 to USD 1,000) and does not require gel packs, dry ice, or active temperature loggers. Customs clearance times of several days do not create a stability concern.

Third, regulatory and coordination. SFDA documentation handling fees and Reserve Meds' concierge fee are itemised separately. On the insurance side, Bupa Arabia, Tawuniya (The Company for Cooperative Insurance), and MedGulf Arabia handle named-patient imports case by case. Some plans reimburse fully when the medicine appears on the insurer's formulary even when the local hospital pharmacy did not have it stocked; others reimburse a percentage; many require pre-authorisation with the clinical justification letter attached. Cash-pay is the default operating posture, with reimbursement sought after delivery if the plan permits. Reserve Meds quotes an indicative range based on the initial intake, then a transparent firm quote with each line item shown separately.

6. Typical timeline for Idhifa in Saudi Arabia

The SFDA timeline for routine PIP cases runs 10 to 21 business days. Idhifa is an ambient oral tablet, so cold-chain transit time does not apply. End-to-end, a typical Idhifa case in the Kingdom runs as follows: 24 to 48 hours from intake to eligibility confirmation by Reserve Meds; 3 to 7 days for the treating hematologist and the dispensing hospital's import pharmacy or an SFDA-licensed specialty importer to assemble the application with the IDH2 mutation testing documentation; 10 to 21 business days for SFDA review (longer for first-time IDH2 inhibitor imports into the institution, where 6 to 10 weeks is plausible); 3 to 5 days for US sourcing through BMS specialty channels and qualified ambient shipment with full DSCSA-compliant chain-of-custody; 1 to 3 days for Saudi customs clearance under the PIP permit; and final receipt and release at the dispensing pharmacy. Subsequent monthly bottles are planned for repeat shipments from the first case, with the continuous-dosing regimen continued until disease progression or unacceptable toxicity.

7. What your physician needs to provide

The clinical justification letter is the cornerstone of the SFDA PIP application. The treating hematologist documents the patient's diagnosis of acute myeloid leukemia in the relapsed or refractory setting, with ICD-10 coding; states the IDH2 mutation testing result with explicit reference to the testing platform (Abbott RealTime IDH2 Assay or an equivalent CLIA-certified IDH2 NGS panel), the mutation variant, the date of pathology, and the laboratory; itemises prior induction and salvage therapy attempts and their outcomes (cytarabine-based regimens, hypomethylating agents, venetoclax-based regimens where attempted); explains why a locally registered alternative is not suitable, with the structural answer that there is no IDH2-selective inhibitor locally registered in the Kingdom and that ivosidenib (Tibsovo, IDH1-selective) is not interchangeable for an IDH2-mutated patient; states the planned dosing regimen (100 mg orally once daily, taken at approximately the same time every day with or without food, with no loading dose, no cycle break, and a minimum six-month trial built into the plan); and describes the monitoring plan with particular emphasis on the boxed warning for differentiation syndrome. The monitoring stack includes vigilance for differentiation syndrome at every visit with highest intensity in the first three months, complete blood count and chemistries including bilirubin at baseline and at least monthly, QT interval monitoring given the label-noted concomitant medication considerations, and management of leukocytosis with hydroxyurea per label without dose interruption.

The letter is co-filed with the physician's SCFHS license verification, the institutional pharmacy license, the requested bottle count and refill plan, and the chain-of-custody plan for the ambient shipment to the dispensing site. Post-import, the treating physician and dispensing pharmacy commit to adverse-event reporting through the SFDA National Pharmacovigilance Center for the full course of therapy.

8. Common questions about Idhifa in Saudi Arabia

Will Bupa Arabia, Tawuniya, or MedGulf cover Idhifa? Each plan handles named-patient imports case by case. Some reimburse fully when the medicine appears on the insurer's formulary even when the local hospital pharmacy did not have it stocked; others reimburse a percentage; many require pre-authorisation with the clinical justification letter attached. The Council of Cooperative Health Insurance (CCHI) governs how these insurers structure their plans. Reserve Meds supplies

the documentation that lets the insurer assess; the claim is yours or your hospital's to file. We do not promise coverage from any insurer.

Will my Ministry of Health-employed hematologist's letter be sufficient? Yes. KSA-licensed physicians at Ministry of Health hospitals, KFSH&RC, KAMC, MNGHA, and other public-sector institutions have full signing authority on PIP applications. Private-sector hematologists at HMG, Saudi German, Fakeeh, Dallah, and similar institutions also have signing authority under their institutional license.

Is IDH2 mutation testing available in the Kingdom? Yes. KFSH&RC, KAMC, and several reference laboratories aligned with the larger private networks run IDH2 testing on certified platforms, including next-generation sequencing panels that report IDH1 and IDH2 status together. The testing laboratory is identified in the PIP filing, and the report is part of the application package.

What is the safety profile I should know about? Idhifa carries a boxed warning for differentiation syndrome, which can be fatal if not recognised and treated. Symptoms include fever, dyspnoea, hypoxia, pulmonary infiltrates, pleural or pericardial effusion, rapid weight gain, peripheral oedema, and renal dysfunction. Patients are counselled to report new respiratory symptoms or rapid weight gain immediately. Other common adverse reactions include nausea, vomiting, decreased appetite, hyperbilirubinemia (indirect), and elevated transaminases. There is no REMS program for Idhifa.

How long until I know if it is working? Median time to first response in the AG221-C-001 trial was approximately 1.9 months, and median time to best response was approximately 3.7 months. The label specifies a minimum six-month trial before declaring lack of response, because the mechanism is differentiation rather than cytoreduction and responses are typically delayed.

Is there a competitor or alternative? For IDH2-mutated relapsed or refractory AML, enasidenib is the only FDA-approved IDH2-selective inhibitor. Ivosidenib (Tibsovo) targets IDH1 and is not interchangeable. Venetoclax-based regimens, hypomethylating agents, and intensive chemotherapy are different mechanisms used in different clinical settings. The treating hematologist makes the selection. Reserve Meds does not endorse one regimen over another.

9. Where Reserve Meds fits in Idhifa cases

Reserve Meds is a US-based concierge coordinator. We do not replace your treating hematologist, SFDA, the dispensing hospital pharmacy or specialty importer, or your insurer. What we do for an Idhifa case is verify eligibility within 24 to 48 hours; supply your physician's team with a documentation kit referencing the FDA prescribing information, the 100 mg once-daily continuous regimen, the IDH2 companion-diagnostic framing, and the SFDA adverse-event reporting reference; align US-side sourcing through BMS specialty distribution channels under DSCSA-compliant chain-of-custody; coordinate ambient shipment with a qualified specialty 3PL; and provide a single named Patient Concierge Coordinator across the case through reorders. Idhifa is a strong fit for the coordination model because the room-temperature handling, the biomarker-confirmed eligibility that simplifies the medical-necessity narrative, and the clearly absent local registration story in the Kingdom mean the case complexity sits primarily in the regulatory and documentation side rather than in physical logistics. No prior Reserve Meds case experience predates this page; standard NPP coordination applies.

10. Next step

If your Kingdom hematologist has confirmed an IDH2 mutation and recommends Idhifa, start the request and we will reach out within 24 to 48 hours.

Reserved for you.

Review & oversight. Content on this page is reviewed by Reserve Meds's clinical and regulatory team. A US-licensed pharmacist reviews every prescription before dispensing. Regulatory posture is informational, not legal advice; case-specific questions route to

retained outside counsel. Review methodology ›

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