Focus: Oncology

PAUL HAWTHORNE, VP and Head, Oncology Business Unit at Sanofi US Inc., talks about how the company is addressing unmet needs in cancer.


Paul Hawthorne

PV: *Sanofi's Oncology division is moving away from its broader disease portfolio and becoming more involved in smaller-prevalence diseases. Why is the company making this move?*

HAWTHORNE: Sanofi Oncology has a broad development portfolio in oncology, hematology, and transplant, including 20 investigational compounds and 15 innovative new molecular entities. We are directing our attention to conditions where there are unmet needs in terms of treatment options. Our portfolio reflects our core R&D beliefs of open innovation and translational medicine and putting human disease at the forefront of drug discovery with the goal of matching molecules with those patients who will benefit most. Open innovation refers to our internal and external collaboration with a network of partners, which includes some of the world's greatest scientific minds, to help us deliver innovative solutions for patients.

The overall goal of Translational Experimental Medicine (TEM) is to improve the speed and probability of success of delivering innovative cancer therapies by fully integrating translational science into drug development paradigms.

Our vision is to be a best-in-class oncology organization focusing our people, science, and solutions to outsmart our common enemy: cancer. Moving into 2013, we are challenging ourselves to see things through the eyes of the patient and to look to solutions both internal and external to the company. The development of our selective JAK2 inhibitor captures the essence of this vision — rationally developing a novel therapeutic to provide an effective new option to a population of patients with a substantial unmet medical need.

PV: *How much of a role will genetics/biomarkers play in this effort?*

HAWTHORNE: Embracing translational medicine allows us to "personalize" our medicines for the patient and better understand the biology of why certain patients respond to a particular therapy, thus developing medicines that are targeted to specific patient populations. We have a fully dedicated translational medicine team focused on predictive biomarkers, molecular/mechanistic proof-of-concept (mPOC), identification of rational combinations, and elucidation of resistance mechanisms, with the sole purpose of identifying patients most likely to respond to a particular therapy.

For example, in developing our JAK2 inhibitor SAR302503, Sanofi leveraged translational science to better understand the pathways and genetic mutations implicated in myelofibrosis — a rare bone marrow cancer — and related blood disorders to identify ways to modify the diseases. The compound has moved rapidly from preclinical development to Phase III because the knowledge gained through translational science helped make the clinical development process more efficient.

Another example is a study about to get under way for our newest chemotherapy agent, Jevtana. The Phase II Taxynergy study explores biomarkers to identify sensitivity and subpopulations of men with metastatic castrate-resistant prostate cancer likely to respond to taxanes. It is also the first study to use circulating tumor cell technology to evaluate taxane chemotherapy sequencing in this group of patients.

PV: *Of your clinical programs, which one are you the most excited about?*

HAWTHORNE: In the short term, I would have to say it's our JAK2 inhibitor in development for the three main myeloproliferative disorders (myelofibrosis, post polycythemia vera, and post essential thrombocythemia).

We are seeing positive results from our translational medicine approach, with a potential new therapy option on the horizon for a group of patients with a high unmet need.

Currently, there are limited treatment options for patients with myelofibrosis. Most available therapies are used to manage symptoms, and none have been shown to reduce or reverse the underlying disease. Many patients do not respond to currently available therapies, and even among those who initially respond, many discontinue treatment due to intolerance or resistance.

SAR302503 is a selective JAK2 inhibitor that has shown activity in patients with myelofibrosis from the initial Phase I study. New Phase II data presented at the 2012 American Society of Hematology annual meeting helped to define the relationship between the dose of SAR302503, its ability to inhibit molecular signaling of JAK2 in the blood of the patients, and its ability to ameliorate the spleen size and alleviate symptoms. These data also confirm a very good pharmacological profile that allows once-a-day dosing. The pivotal Phase III study, JAKARTA, is currently under way; enrollment of 289 patients has been completed and results are expected in the second quarter of 2013.

PV: *Do you think oncology research in general within the industry will begin to address smaller patient populations?*

HAWTHORNE: Sanofi Oncology is dedicated to translating science into effective therapeutics that address unmet medical needs for cancer and organ transplant patients. Our goal is to truly make a difference in the lives of patients by bringing the right medicines to the right patients and address patient medical needs that have been overlooked by the blockbuster model of drug development.

PV: *Where do you think there is the most unmet need?*

HAWTHORNE: In the oncology industry, in order to really impact the cancer landscape in a positive way, we have to look at the unmet needs and apply our talent and expertise to provide solutions to advance the field. This is how we define innovation. With cancer being more than 100 different diseases, there are many unmet needs.

Myeloproliferative diseases such as myelofibrosis are certainly one area of substantial unmet need, as current therapies are mainly palliative or may not be well tolerated by a large number of patients.

Zaltrap (ziv-aflibercept), which was approved in August by the FDA after a priority review and is now under review with the European Medicines Agency, is a much-needed new therapy option for patients with metastatic colorectal cancer who progress after an oxaliplatin-containing chemotherapy regimen. Survival statistics for this stage of colorectal cancer are dismal and there are limited treatment options.

Patient needs extend beyond medicines. Sanofi programs such as Jevtana C.A.R.E.S., and Patient Connections, encourage patients to better engage with their own health, educate patients about their conditions and treatment options, and provide access to our medicines. PV

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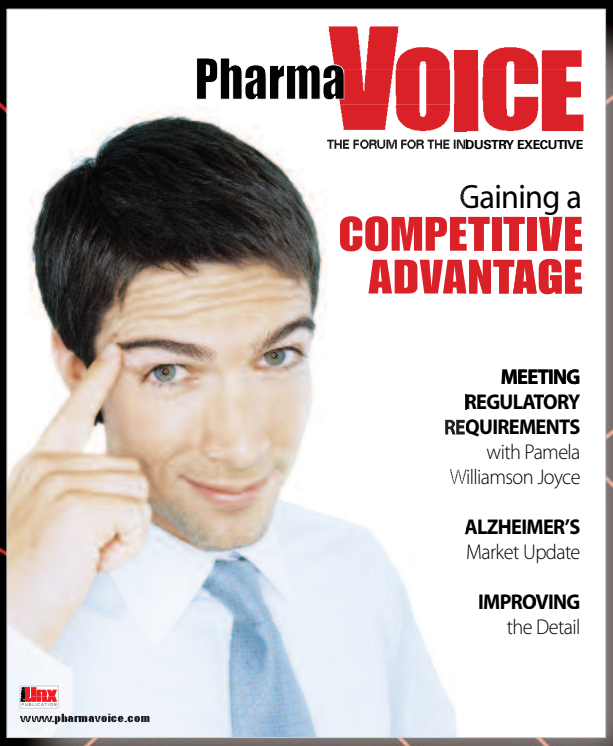

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Cancer Focus

At Sanofi Oncology the aim is to combat cancer in all its different forms by carrying out research on the different pathways involved in the development, growth, and propagation of cancer cells.

More than 12 million people are diagnosed with cancer worldwide every year.

According to Sanofi Oncology, patients lie at the heart of its research and development efforts. With a focus on partnership and innovation to discover new agents and new strategies in the fight against cancer, Sanofi Oncology is banking on the power of translational medicine and working internally and externally to strengthen cooperation between all researchers whose work is focused on patients.

With eight products already on the market — Elitek, Eloxatin, Jevtana, Leukine, Mozobil, Taxotere, Thymoglobulin, and Zaltrap — Sanofi Oncology has a broad development portfolio in oncology, hematology, and transplant, including 20 investigational compounds and 15 innovative new molecular entities.

Additionally, the company is supporting its R&D efforts with a variety of patient support programs.

"Patient needs extend beyond medicines," says Paul Hawthorne, VP and head, oncology business unit, Sanofi US Inc. "Sanofi programs, such as Jevtana C.A.R.E.S. and Patient Connection, encourage patients to better engage with their own health, gain education about their conditions and treatment options, and receive information about access to our medicines."

A multidisciplinary team of Sanofi researchers, clinicians, pharmacists, toxicologists, and representatives from regulatory affairs and marketing is dedicated to each drug candidate for its entire development phase. These team members work together to identify the expectations of patients and the medical community and use this knowledge to design each investigational agent's development program. PV

Sanofi Oncology Pipeline

Phase I

Iniparib (BSI-201)*
Areas under investigation: NSCLC, sarcoma, breast, uterine, lung, ovarian, solid tumors
Class: A novel investigational oncology agent

Ombrabulin (AVE8062)
(Licensed from Ajinomoto)
Areas under investigation: Soft tissue sarcoma, NSCLC, ovarian, solid tumors
Class: Vascular-disrupting agent

SAR153192 (REGN421)
(Regeneron, codevelopment collaborator)
Areas under investigation: Solid tumors
Class: Delta-like-ligand-4 monoclonal antibody

SAR307746 (REGN910)
Areas under investigation: Solid tumors
Class: Angiopoitentin-2 monoclonal antibody

SAR245408
Areas under investigation: Endometrial, breast, solid tumors, glioblastoma, lymphoma
Class: PI3K inhibitor

SAR245409
Areas under investigation: Malignant glioma, breast, solid tumors, CLL, NHL
Class: Dual PI3K and mTOR inhibitor

SAR256212 (MM-121)
(Merrimack, codevelopment partner)
Areas under investigation: Solid tumors, breast, NSCLC, ovarian
Class: Anti-ErbB3 monoclonal antibody

SAR566658
(ImmunoGen, alliance partner)
Areas under investigation: Solid tumors
Class: Maytansine-loaded anti-DS6 monoclonal antibody

SAR650984
(ImmunoGen, alliance partner)
Areas under investigation: Hematologic malignancies
Class: Anti-CD38 monoclonal antibody

Genz-644282
Areas under investigation: Solid tumors
Class: Small molecule non-comptothecin topoisomerase I inhibitor

SAR125844
Areas under investigation: Solid tumors
Class: MET Inhibitor

SAR3419
(ImmunoGen, alliance partner)
Areas under investigation: B-cell malignancies: ALL, DLBCL, and NHL
Class: Maytansine-loaded anti-CD19 monoclonal

Phase II

Iniparibb (BSI-201)**
Areas under investigation: NSCLC, sarcoma, breast, uterine, lung, ovarian, solid tumors
Class: A novel investigational oncology agent

Ombrabulin (AVE8062)
(Licensed from Ajinomoto)
Areas under investigation: Soft tissue sarcoma, NSCLC, ovarian, solid tumors
Class: Vascular-disrupting agent

SAR302503 (TG101348)
Areas under investigation: Intermediate-2 or high-risk myelofibrosis, Polycythemia Vera, essential thrombocythemia, ruxolitinib-resistant or intolerant myelofibrosis
Class: JAK2 inhibitor

SAR245408
Areas under investigation: Endometrial, breast, solid tumors, glioblastoma, lymphoma
Class: PI3K inhibitor

SAR245409
Areas under investigation: Malignant glioma, breast, solid tumors, CLL, NHL
Class: Dual PI3K and mTOR inhibitor

SAR256212 (MM-121)
(Merrimack, codevelopment partner)
Areas under investigation: Solid tumors, breast, NSCLC, ovarian
Class: Anti-ErbB3 monoclonal antibody

SAR3419
(ImmunoGen, alliance partner)
Areas under investigation: B-cell malignancies: ALL, DLBCL, and NHL
Class: Maytansine-loaded anti-CD19 monoclonal antibody

Phase III

Iniparibа * (BSI-201)
Areas under investigation: NSCLC, sarcoma, breast, uterine, lung, ovarian, solid tumors
Class: A novel investigational oncology agent

Ombrabulin (AVE8062)
(Licensed from Ajinomoto)
Areas under investigation: Soft tissue sarcoma, NSCLC, ovarian, solid tumors
Class: Vascular-disrupting agent

SAR302503 (TG101348)
Areas under investigation: Intermediate-2 or high-risk myelofibrosis, Polycythemia Vera, essential thrombocythemia, ruxolitinib-resistant or intolerant myelofibrosis
Class: JAK2 inhibitor

Notes: * Iniparib is the United States adopted Name (USAN) for BSI-201. ** New drug application submitted by the FDA.

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