LETTER TO OUR SHAREHOLDERS



Vector of innovation.

NOVEMBER 2019



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MESSAGE FROM THE CHAIRMAN Philippe Genne, Chairman and CEO



The alignment of planets is more topical than ever at the end of the year, with all due respect to the spell casters.

In praise of resilient shareholders

Despite the viral infections—including both the flu virus and shorttermism—currently on the rampage, Oncodesign is in great shape 25 years after it was founded. Our June health bulletin shows we have a real spring in our step, with our revenue recording a substantial increase and our operating performance in positive territory, while we again devoted a hefty €5 million to R&D spending in the first half of 2019. Our development pipeline containing our first drug candidates is constantly expanding, with the RIPK2 program at the most advanced stage. And we have launched a new collaborative project with Servier concerning the LRRK2 kinase as a treatment for Parkinson's disease on very firm foundations.

This new project gained considerable attention and was highly commended in the truly transformational and high value creating deal category of the 2019 European Lifestars Awards.

Naturally, we continued to manage our portfolio actively, making certain adjustments. But these are the result of deliberate choices, such as bringing to an end development of ALK1 in oncology and focusing on ALK2 in fibrodysplasia ossificans progressiva (FOP). They also reflect decisions made by third parties, such as the end of collaboration with UCB and the natural conclusion of the collaborative Imakinib project. Yet our ability to adapt continuously to our environment while holding to a firm strategic course is what sets Oncodesign apart. Things have continued to slot into place in the final months of the year—despite what the naysayers predicted.

For some time now, I've had a very keen interest in Japan, where we are fortunate to be working with a large number of pharmaceutical companies. I happened to be near Tokyo when Typhoon Hagibis struck the country during the Rugby World Cup. The Japanese never complained, before or after the event, but simply got on with the job of advance planning or rebuilding. "Fear doesn't avoid the danger" is far more than just an old saying. In my view, the Japanese are a perfect embodiment of resilience—an essential quality when you are an entrepreneur or an investor.

Likewise, we remain fully focused on our long-term objectives because it is not in our nature at Oncodesign to give up. I would like to thank you for your continued trust as we calmly and confidently build for the future together.

See you very soon,

Philippe Genne

ARTIFICIAL INTELLIGENCE (AI) POISED TO PLAY A KEY ROLE IN THE FUTURE OF MEDICINE

The new possibilities created by using artificial intelligence (AI) in healthcare hold great promise for patient treatments over the coming years with the advent of safe and personalized therapies, reliable new diagnostics systems and more effective ways of conducting R&D to help meet the priority of cutting healthcare costs. Initial results have lent weight to the view that these new technologies have the ability to revolutionize the future of medicine. AI looks set to be employed in every field, from the management of information flows through to drug discovery.

The development of increasingly powerful hardware platforms, networked sensors and systems, and the exponential growth in data volumes have helped to improve AI systems, which are now capable of factoring in parameters specific to each patient. The first applications emerged seven years ago with the advent of patient monitoring, lifestyle control and treatment solutions, virtual assistants and hospital management systems.

To date, hospital data flow management is the segment that has benefited the most from these intelligent systems. The solutions on the market have been successful as a result of the rapid uptake of chatbots and smart speakers, administrative tools, such as appointment booking, and insurance coverage checking. At the same time, clinical research is another segment in which AI has been actively employed. It is used to help design clinical protocols, identify clinical facilities, enroll patients, stratify patients, collect and analyze data, and make regulatory submissions.

Personalized patient therapies or precision medicine is an area that has attracted massive investment to develop new tools and systems. The potential applications are extremely broad, ranging from prevention through to diagnostic assistance, screening, prediction of therapeutic response or resistance to the current therapy, adaptive medicine (adjusting the treatment protocol to developments in the patient's condition), data collection and analysis employing connected objects, pharmacovigilance and, last but not least, evidence to support reimbursements (Real-World Evidence).

Drug discovery is another segment in which AI solutions are gaining a foothold, and they are promising given the priorities in the area. There have been a large number of initiatives in the area over the past two years involving research teams, start-ups, pharmaceutical groups, biotech companies and so on. They are all making massive investments to unearth new therapeutic targets, develop more effective personalized therapies and reposition existing drugs.

Broadly speaking, the market for artificial intelligence technologies in the healthcare segment was worth an estimated \$2.1 billion in 2018. It is forecast to grow by 50.2% every year, reaching an estimated \$36.1 billion by 2025¹. This stunning pace of growth is being driven by stakeholders in the drug value chain, digital companies such as the GAFAMIs², and various specialized start-ups. Drug regulators (FDA, EMA) also have a key role to play in fostering the adoption and development of AI technologies in new drug development processes³.

In the United States, venture capital funds invested \$1.08 billion in start-ups specialized in AI for drug discovery during 2018, and a further \$699 million in the first half of 2019⁴. Fast-growing ecosystems are taking shape in California, Boston and on the US north-eastern seaboard, Cambridge (UK), Montreal and Toronto (Canada), Basel and Lausanne (Switzerland), and Paris.

Given the revolutionary change that AI is bringing about, Oncodesign has put AI at the center of its development for four years now.

^{1 -} Artificial Intelligence in Healthcare Market Report, Markets & markets, December 2018

^{2 -} Google Amazon Facebook Apple Microsoft IBM

³⁻ Artificial intelligence in drug development predicted to grow: DIA-Tufts study – M. Fassbender, 2019

⁴⁻ https://www.bloomberg.com/news/features/2019-07-15/google-ai-could-challenge-big-pharma-in-drug-discovery

WITH ONCOSNIPE®, ONCODESIGN POSSESSES A GROUND-BREAKING AI PROJECT HELPING TO MAKE THERAPEUTIC INNOVATION MORE EFFICIENT

Oncodesign was one of the first biopharmaceutical companies to get involved in the development of new AI-based drug discovery technologies in 2015. Ever since, Oncodesign's goal has been to develop and integrate AI tools for identifying patients unresponsive or resistant to anti-cancer therapies using its precision medicine platform. Oncodesign hired a laboratory manager to set up a data science lab within the company. Clinical centers and industry partners rapidly joined its initiative, giving rise to the OncoSNIPE® project in 2017, which was selected and financed by BPI.



Source: Oncodesign

OncoSNIPE® in numbers

ONCOSNIPE®: IDENTIFICATION OF PATIENTS RESISTANT OR UNRESPONSIVE TO ANTI-CANCER THERAPIES



OncoSNIPE® : lower the therapeutic failure rate *Source: Oncodesign*

Harnessing insights from bioinformatics, artificial intelligence, statistical learning and semantic enrichment, the OncoSNIPE[®] project is designed to identify and characterize patients resistant or unresponsive to anti-cancer therapies.

While there are many different applications, such as providing guidance to therapeutic specialists on how to treat a patient or to a pharmaceutical firm on how to develop new drugs, the ultimate objective is always the same:

to reduce therapeutic failure rates.

Clinical, genomic and medical imaging data from 600 patients is collected longitudinally, which means on several occasions during each patient's course of treatment. It is then analyzed and used as input into an artificial intelligence system so that it can learn to recognize which patients are likely to be unresponsive to treatments or to become resistant after an initial response, and to characterize them. The role of the medical experts partnering with the project is to validate the results of the model and thus to confirm its effectiveness.

This data will then be used to identify new targets and mechanisms of actions associated with resistance phenomena or to guide new therapeutic developments.



Figure 1: OncoSNIPE®, harnessing insights from artificial intelligence to identify cohorts of resistant patients



The five-year project is being conducted in partnership with:

- Expert System, a specialist in semantic enrichment technologies that develops pseudonymization tools;
- Sword, an integrator of data and IT solutions, which designed ConSoRe, a tool used by the Unicancer Federation of Centers for the Fight Against Cancer in France¹;
- Acobiom, a biotech company specialized in the development of precision medicine diagnostics kits;
- seven academic institutions, including four cancer research centers—Strasbourg university hospital, the Centre Georges François Leclerc (Dijon), the Curie Institute (Paris), the Centre Léon Bérard (Lyon), the Institut Paoli Calmettes (Marseille), the Institut Godinot (Reims) and the Unicancer Federation.

1 - Unicancer is the only French hospital network focused solely on combating cancer. It encompasses 18 French cancer centers, which are private non-profit healthcare institutions located across 20 hospital locations in France. Unicancer is the only nationwide hospital federation in France dedicated solely to cancer treatment. It is also Europe's leading academic sponsor of clinical trials in oncology

oncoSNIPE[®]: a \in 12 million investment with practical applications in oncology anticipated by 2022

Overall, the OncoSNIPE[®] project represents an aggregate investment of €12 million. Three indications representing resistance mechanisms in oncology are being studied—triple negative breast cancer, pancreatic cancer and non-small cell lung cancer. These three types of cancer represent very different resistance mechanisms, paving the way for the algorithms developed by OncoSNIPE[®] to be extended to other cancer indications from 2022.

ARTIFICIAL INTELLIGENCE, WHICH LIES AT THE HEART OF ONCODESIGN'S PRECISION MEDICINE PLATFORM, IS OPENING UP NEW POSSIBILITIES

The investments in OncoSNIPE[®] will significantly augment Oncodesign's ability to innovate. Once the project is completed, Oncodesign will be able to harness the clinical data studied in OncoSNIPE[®] to identify therapeutic targets associated with patients resistant or unresponsive to existing treatments. These therapeutic targets will play a crucial part in guiding the discovery of new precision therapies in oncology.

The algorithms used to recognize resistance or unresponsiveness will be used by the oncologists partnering with the project when they take on new patients, since they should help to predict whether they will be unresponsive or whether they will become resistant. OncoSNIPE[®] will thus underpin a new type of service for healthcare institutions, supporting the diagnostic assessment of resistant diseases as part of the patient treatment process. The same service range can be offered in connection with clinical trials to facilitate the enrollment of patient sub-populations resistant to certain cancer treatments.

In drug discovery, few companies have allocated such a large proportion of their R&D programs to AI as Oncodesign has done.



DIFFERENT PERSPECTIVES, AN INTERVIEW WITH DR. MARINE GILABERT, ONCOLOGIST AT THE MARSEILLE CANCER RESEARCH INSTITUTE (CRCM)



"We have high hopes for the highly ambitious OncoSNIPE project."

THE LARGE NUMBER OF DIFFERENT TYPES OF CANCER AND THEIR DIVERSITY REPRESENTS A MAJOR CHALLENGE

"Despite the recent surgical advances and the arrival of targeted chemotherapy and/or therapy combinations, pancreatic cancers remain hard to treat.

Two patients who may have the same profile when diagnosed may experience very different outcomes, which cannot be predicted using existing scientific tools.

The same observation applies to therapeutic response rates. Knowing which treatment option is best suited to which patient and which tumor is one of the key issues with pancreatic adenocarcinoma. Identifying clinically effective biomarkers that can be used to decide how to treat a patient taking into account tumoral heterogeneity and drug resistance poses a real challenge.

ONCOSNIPE[®]: POOLING TALENTS TO LOWER THERAPY FAILURE RATES

That was the backdrop against which the OncoSNIPE[®] project was launched in 2018. Using primary cultures (cells grown in vitro) based on tumor biopsies from consenting patients, we perform in-depth analysis of the DNA, DNR, proteins and tumor proliferation signaling pathways of the tumor cells and on their cell metabolism, behavior/ interactions with other organism cells and the principal cell factors involved in treatment resistance.

The project has recently got underway with several hospital centers and the CRCM's pancreatic cancer research platform run by Dr. Juan Iovanna and Dr. Dusetti collaborating.

Searches for biomarkers will be conducted both in the blood (blood samples taken) to analyze circulating cells/ tumor DNA and in the tumor itself.



Marine GILABERT MD, PhD oncologist - Institut Paoli Calmette

Ultimately, we would like to be able to identify a patient's degree of sensitivity to a chemotherapy molecule with just a blood test using these techniques so we can select the most appropriate therapeutic protocol.

We have high hopes for this very ambitious project. We genuinely believe it will advance knowledge of pancreatic tumors and their treatments."

Read our interviews about artificial intelligence

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COMBATING RARE DISEASES USING THE NANOCYCLIX® PLATFORM: FIBRODYSPLASIA OSSIFICANS PROGRESSIVA

Fibrodysplasia ossificans progressiva (FOP) is a genetic disease that affects less than 0.001% of the world's population¹. Based on the scientific advances made under the leadership of Prof. Kaplan² (Faculty of Medicine, Pennsylvania, US) and Prof. Peter Ten Dijke (Medical Research Institute, Leiden, The Netherlands), Oncodesign has identified a promising new avenue for the development of a treatment for FOP.

FOP. A GENETIC DISEASE FOR WHICH NO CURE EXISTS AT PRESENT

FOP is a rare genetic disease responsible for the progressive transformation of muscular cells into bones (heterotopic ossification). The cause identified in 2006 by the research team led by Prof. Kaplan is a single-gene mutation in the gene coding the ALK2 kinase protein (chiefly R206H), causing overactivation of a signaling pathway involved in osteogenesis in 97% of patients.

The first clinical symptoms are observed in patients aged 4-5 through X-ray analysis. Flare-ups are triggered largely through contusions, injuries, infections and miscellaneous inflammatory conditions. The patient's condition deteriorates slowly until their posture becomes fixed at around the age of 18 and they are completely immobilized. The life expectancy of patients with the disease is just 40-45 years. To date, there is no known treatment for the condition, and surgery is ineffective at slowing the development of additional ossification.

A NEW GENERATION OF KINASE INHIBITORS PROMOTING THERAPEUTIC INNOVATION

Oncodesign has been working for several years on Nanocyclix[®], a proprietary platform providing access to selective, powerful molecules possessing attractive intrinsic properties for future drugs. Through research activities conducted since 2014, Oncodesign has identified ALK2 kinase inhibitors demonstrating a high level of activity in phenotype cell testing related to FOP. This work was performed in collaboration with globally renowned research institutes in the field. It culminated in the publication of an article in last month's Journal of Bone and Mineral Research³.

By harnessing the expertise and know-how of the Drug Discovery teams in optimizing small molecules for the selection of drug candidates, Oncodesign identified a pharmacological tool that can be used to assess the relevance of these inhibitors in an animal model that spontaneously develops heterotopic ossification similar to that observed in humans.

Jan Hoflack, Chief Scientific Officer and Chief Operating Officer, added: "Our Nanocyclix[®] platform enabled us to identify very powerful ALK2 kinase inhibitors, which appear to be specific to the mutant form of this kinase responsible for FOP. That sets our molecules apart from those of our competitors and has attracted interest from potential partners. FOP is an extremely rare, devastating disease, and that's why we want to push ahead with this program, currently at the advanced lead stage, under a partnership with major industry players or patients' associations."

Jan Hoflack attended the FOP Drug Development Forum in Orlando (US) on November 13 and 14. Academic and industry researchers from around the world came together at the fourth edition of this forum to share their latest results concerning FOP.

^{1 -} Orphanet, FOP Disease

^{2 -} Shore EM, Xu M, Feldman GJ, et al. A recurrent mutation in the BMP type I receptor ACVR1 causes inherited and sporadic fibrodysplasia ossificans progressiva. Nature Genet. 2006;38:525–527

^{3 -} Development of macrocycle kinase inhibitors for ALK2 using Fibrodysplasia ossificans progressiva-derived endothelial cells Journal of Bone and Mineral Research - the scientific article will be published in the journal over the next few weeks, but is already available online at: https://doi.org/10.1002/jbm4.10230

Gonzalo Sánchez-Duffhues, Eleanor Williams, Pascal Benderitter, Valeria Orlova, Michiel van Wijhe, Amaya Garcia de Vinuesa, Georgina Kerr, Josselin Caradec, Kirsten Lodder, Hetty C. de Boer, Marie-José Goumans, Elisabeth M.W. Eekhoff, Antonio Morales-Piga, Javier Bachiller-Corral, Pieter Koolwijk, Alex N. Bullock, Jan Hoflack, Peter ten Dijke

"This publication is the result of collaboration between Oncodesign and the Leiden University Medical Centre (LUMC) in fibrodysplasia ossificans progressiva. Oncodesign's compounds demonstrated significant inhibition of osteogenic differentiation in our phenotype testing in addition to a specific pathway that we had not seen with any of the other small molecule compounds we assessed. The potential of these compounds, which could provide an unprecedented therapeutic solution for patients, will be tested through evaluation by the pharmacological tool", said Prof. Peter Ten Dijke of the Leiden University Medical Centre in the Netherlands.

WHAT'S THE LATEST NEWS ON THE FOP FRONT?

In October 2019, Ipsen and Blueprint Medicines announced an exclusive licensing agreement for the development and marketing of BLU-782 in the treatment of fibrodysplasia ossificans progressiva. Under the deal, Ipsen has added BLU-782, a highly selective ALK2 receptor currently under clinical development as a potential treatment for FOP, to its Rare Diseases portfolio. In addition, Blueprint Medicines will be eligible to receive up to \$535 million (upfront cash payment of \$25 million and up to \$510 million in potential milestone payments related to specified development, regulatory and sales-based milestones) other payment and percentage royalties.

This deal underlines the pharma industry's interest in this type of molecule and the scale of such a partnership for the clinical development of a treatment in the fibrodysplasia ossificans progressiva indication.

In November 2019, the LUMC and Oncodesign published a joint article on ALK2 in the highly renowned journal of **The American Society for Bone and Mineral Research** entitled "Development of Macrocycle Kinase Inhibitors for ALK2 Using Fibrodysplasia Ossificans Progressiva-Derived Endothelial Cells"



For more information

International FOP Association: https://www.ifopa.org/ Reference center for constitutional bone diseases: http://www.maladiesrares-necker.aphp.fr/moc/



LATEST NEWS



LE JOURNAL DU PALAIS - TUESDAY, NOVEMBER 5, 2019 Oncodesign goes from strength to strength

The Dijon biopharmaceutical group specializing in precision medicine, Oncodesign, announces a further acceleration in the growth of its turnover. In the first half of 2019, the company created by Dr. Philippe Genne, more than 20 years ago, recorded an increase of almost 52% compared to the previous year to 14 million euros. In detail, the Service activity crossed the 10 million euro mark thanks to an increase of 15% over the first six months of the year, while the Partnership activity saw its turnover multiplied by seven. One result, in particular possible thanks to a strategic partnership signed in March 2019 with Servier, for the development of LRRK2 kinase inhibitors in Parkinson's disease. Finally, the company, which today employs 232 people, had cash of € 13.3 million as of June 30 - up 36% from June 30, 2018. Oncodesign announced at the end of June that it had identified a molecule that can allow the treatment of autoimmune diseases such as Crohn's disease, rheumatoid arthritis or multiple sclerosis. thanks to a strategic partnership signed in March 2019 with Servier, for the development of LRRK2 kinase inhibitors in Parkinson's disease. Finally, the company, which today employs 232 people, had cash of € 13.3 million as of June 30 - up 36% from June 30, 2018. Oncodesign announced at the end of June that it had identified a molecule that can allow the treatment of autoimmune diseases such as Crohn's disease, rheumatoid arthritis or multiple sclerosis.



BOURSIER.COM - THURSDAY, OCTOBER 24, 2019

Oncodesign: promising results for the FOP treatment

This publication is an endorsement of kinase research and Oncodesign's technology for exploring this field. Using its Nanocyclix[®] platform, Oncodesign has identified highly selective inhibitors of the ALK2 kinase and its mutant form. Work conducted in conjunction with Prof. Bullock (University of Oxford, UK) and Prof. Ten Dijke has demonstrated significant inhibition of osteogenic differentiation/reprogramming in cells derived from FOP patients carrying the mutation.



LATEST NEWS (continued)



FLASH INFOS CÔTE D'OR – WEDNESDAY, OCTOBER 16, 2019

Oncodesign's growth and development continues

Oncodesign, the biotechnology company, has continued to grow and develop. Its top-line performance gained real traction in the first half of the year, and it has reiterated its target of €40 million in revenue next year. Service revenue rose 15%, and its R&D is supporting the Drug Discovery programs and the Partnership & Licensing business. A preclinical drug candidate is expected by the end of the year for the treatment of autoimmune diseases. Its profitability improved significantly, too.

MIND HEALTH - WEDNESDAY, OCTOBER 2, 2019

How the healthcare industry is embracing artificial intelligence

In clinical research, Oncodesign plans to use artificial intelligence primarily to identify and characterize patients resistant to anti-cancer therapies so it can develop effective precision medicine treatments for cancers resistant to existing therapies. The biopharmaceutical company is part of the three-year OncoSNIPE[®] project launched in October 2017.

"The project is currently at the patient enrollment stage, leading to the collection and integration of data as part of a clinical trial in three indications—breast, lung and pancreatic cancer", explained Philippe Genne, Chairman and CEO of Oncodesign. The aim is for the program to enroll 200 patients in each of these indications.

BOURSIER.COM - THURSDAY SEPTEMBER 26, 2019

Positive interims for Oncodesign

Oncodesign recorded an interim profit of €0.51 million, compared with a loss of €3.53 million in the first half of 2018. Goodwill amortization reflected the positive impact of €0.5 million deriving from amortization of the negative goodwill associated with the François Hyafil center (€1 million p.a. over 7 years). Consolidated net income came to €0.73 million in the first half of 2019, compared to a loss of €3.42 million in the same period of 2018. Cash and cash equivalents totaled €13.3 million at June 30, 2019 not including the €3.3 million research tax credit due in respect of 2018. Oncodesign has reiterated its target of €40 million in revenue together with positive operating income in 2020.

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BROKERS' RATING



Broker	Analyst	Date	Recommendation
	Gilbert Ferrand	September 27, 2019	Buy
Kepler Cheuvreux	Thomas Guillot	September 27, 2019	Buy
CM-CIC Market Solutions	Fanny Meindre	September 27, 2019	N/A
Bryan, Garnier & Co	Gary Waanders	September 27, 2019	Buy



News: News: Oncodesign & servier commended in the "Deal of the Year" category of the Lifestars Awards partners

• Value Award

This award recognizes the teams and organizations who have executed a truly transformational and high value creating deal for both the company and the wider industry. The deal could be a licensing agreement, co-development or a creative alliance or partnership.

Judges

The members of the judging faculty of the 2019 Lifestars Awards were chosen for their wealth of industry experience and strength of their cross-border knowledge. They are selected from a geographically diverse pool of leading investors, pharma, global advisory, law firms, professional and financial services, contract services, and PR and IR Firms.

THE NOTEBOOK OF SHAREHOLDER



Oncodesign & the stock market

Euronext Growth Paris		
ISIN Code	FR0011766229	
Number of shares	6,818,412	
Market capitalization	46 M€*	
Share price	6,78€*	
12 month high/low	10,7 € /6,34 €	
*Data at October. 17. 2019		



ONCODESIGN CAPITAL STRUCTURE at December 31, 2018



2019 CALENDAR



Publication of FY 2019 Revenues:

January 30, 2020 (after stock market closing)

Scientific conferences

- EBF, Barcelona, November 20-2
- BioFit, Marseille, December 10-11

DOCUMENTATION



Our 2019 half-year financial report is available in the Investor section of our website:





Flash this QRCode to access the investor section.

A TEAM ATTENTIVE TO OUR SHAREHOLDERS



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AT ONCODESIGN, WE TAKE THE PRIVACY OF YOUR PERSONAL DATA VERY SERIOUSLY

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In line with the French Data Protection Act of January 6, 1978 as amended, you have a right to access and amend the data held concerning you.

You can access the information we hold about you by contacting us at oncodesign@newcap.eu CNIL reference 2102182 v 0.

ONCODESIGN AT A GLANCE

Oncodesign, a vector of innovation, is a biopharma company whose mission is to find new avenues of treatment using precision medicine based on its unique patient-centered innovation model.



OUR MISSION AND OUR TECHNOLOGICAL STRENGTH

"Discover innovative new therapies effective against cancer and serious illnesses with unmet medical needs." Philippe Genne - Oncodesign Chairman & CEO.

Oncodesign's specific strength lies in its technology continuum, which covers the entire molecule discovery cycle from identification of resistant patient populations right through to the drug candidate. Oncodesign puts the patient at the heart of its technology continuum to target the problem of inherent or acquired therapeutic resistance. This innovation model sets us apart.



- It is based on our three strategic activities:
- 1- Etiology of diseases
- 2- Discovery of new therapeutic target/
- molecule combinations
- 3- Experimentation of new treatments.

OUR BUSINESS MODEL

Oncodesign leverages its strategic activities through three types of contractual arrangement:



What is a kinase inhibitor?

A kinase is a protein that speeds up chemical reactions in the body. Kinase deregulation is the cause of more than 400 diseases. This deregulation can be resolved by binding a small molecule to the kinase to block its activity.

What is a radiotracer?

What is a biomarker?



NOTES

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