

French Startup Alcediag Jumps Into Psychiatric Molecular Diagnostic Market

Aug 11, 2016 | [Elizabeth Newbern](#)

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NEW YORK (GenomeWeb) – French molecular diagnostics firm Alcediag has begun developing a portfolio of molecular tests for psychiatric conditions and medications, starting with its Editox test for identifying pharmaceutical compounds that induce severe depression or suicide in patients.

The firm, which was founded in 2014 and is a subsidiary of French diversified technologies firm Alcen, also is developing an *in vitro* diagnostic tool to help clinicians diagnose patients with depression and/or those at suicide risk. It aims to launch that test, called Editdiag, in the next couple of years.

Both technologies use the same basic science. "In human RNA, there are some locations where you can find editing," Alcediag President Alexandra Prioux told GenomeWeb. In the case of psychiatric pathologies — such as depression and suicide — RNA editing is altered and creates areas on an RNA strand that are either more or less edited than in "normal" circumstances, she explained.

Alcediag's technology analyzes RNA strands and identifies altered RNA editing that is associated with depression and suicide risk. The company has identified five RNA biomarkers that it uses in its diagnostic technology.

Its first product, Editox, is an *in vitro* cell line assay developed to identify the risk for a compound to induce severe depression or suicide for patients, Prioux said.

"We use a neuroblastoma cell line (SH-SY5Y), which is used as a 'model' of a [functioning human brain]," Prioux said in a follow-up email. Editox works by putting these cells in contact with compounds of interest, usually at three different concentrations, and then analyzing how and if RNA editing has been altered when compared to a cell line that was not exposed to a chemical compound, she explained.

"In order to define the potential risk of a compound, we use a proprietary algorithm as well as what we would call a 'standard at-risk profile,'" she said. This allows Alcediag to define the level of risk, which is reported as low, moderate, or high risk for patients.

Alcediag has been in discussions with several pharmaceutical companies to talk about the possibility of using Editox to test the molecules they are developing for psychiatric treatment, Prioux told GenomeWeb. "It will allow them to mitigate the risks linked to adverse psychiatric side effects while limiting the use of animals in pre-clinical phases," she said.

Currently, the firm is marketing the Editox test itself, although it may consider marketing agreements down the line, Prioux said.

The firm's primary competition in this space will come from Assurex Health, which was [recently acquired by Myriad Genetics](#). Assurex markets GeneSight, a test that analyzes a person's cheek swab sample for a panel of PGx markers that doctors can use to personalize their patients' antipsychotic and antidepressant medications. This test "aims to stratify patients, or identify patients' response to a treatment," Prioux noted. "They also claim that they are able to manage adverse side effects."

While both companies compete in this space, Prioux indicated that she doesn't believe that the two products are in direct competition at present. "The main difference between the Assurex technology and Alcediag's is that Assurex is looking at genetic mechanisms while we are looking at epigenetic mechanisms," Prioux said in an email. Alcediag's tests are early post-transcriptomic, which gives it the advantage of providing information with only a short delay on a patient's response to treatment, she said. While the genetic background of a patient is important, it doesn't allow insight into whether a gene is expressed.

Additionally, the Editdiag test that Alcediag is developing will allow clinicians to diagnose mental illnesses, which is not in Assurex's scope, Prioux claimed.

Another psychiatric pharmacogenomics firm called CNSDose [launched earlier this year](#) with plans to introduce a depression medication dosing test that could compete with the Editox test.

The firm's Editdiag test, which is currently in development with a target launch date in 2019, interrogates a panel of five specific RNA biomarkers taken from a small blood sample, a few milliliters, using next-generation sequencing on Illumina platforms, said Prioux. The firm believes these specific types of RNA markers are unique to patients with particular psychiatric disorders.

Alcediag has reported some results from a small clinical trial involving a few dozen patients recruited from two centers in Spain and France involved in a psychiatric emergencies prospective study. The patients were divided into two groups: one group of patients that suffer from major depression but have no history of suicide attempt, and another group of patients that suffer from major depression and have made suicide attempts.

The results showed that Alcediag's five biomarkers could diagnose depression and/or suicide risk with 95 percent specificity and 89 percent sensitivity.

When a patient comes into the "psychiatric emergency room" there is a 48-hour period in which psychiatrists have to decide what the best course of action is — which may be to send them back home or to hospitalize them for a longer period, Prioux explained. Traditionally, doctors have patients fill out questionnaires, interview them, and interview family members to get enough data to make a decision. "[These tests] give them another way to evaluate the patient," Prioux said, adding that a diagnostic tool that could help diagnose and monitor depression and suicide risk "could have a tremendous and positive impact on patients."

Among adults, major depression is one of the most common mental disorders in the United States, according to the National Institutes of Health. Major depression creates a higher risk of suicide, which took more than 42,000 lives in the United States in 2014, according to the US Centers for Disease Control.

After the Editdiag test rolls out onto the market in a few years, Alcediag has plans to expand.

"We know that RNA editing is involved in many areas, both psychiatric and non-psychiatric," Prioux said. Future diagnostic tools sold by the firm will use different RNA biomarkers, but use the same basic technology, she added.

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