



BMSystems and ASFC reinforce their strategic collaboration to accelerate the development of the first-in-class ME/CFS therapeutic CADI-T1031 in response to ME/CFS and the related Post Covid-19 Syndrome.

Paris, France September 21, 2020: On September 15, 2020 *Bio-Modeling Systems* (BMSystems) and the *French ME/CFS (Myalgic Encephalomyelitis/Chronic Fatigue Syndrome) patient Association* (ASFC) reinforced their strategic collaboration to accelerate the development of CADI-T1031 by signing an agreement covering:

1. patient identification and stratification protocols
2. continuous patient information on the therapeutic program
3. co-development of a therapeutic solution
4. active support for clinical development through a therapeutic spin-off to be created by the end of 2020.

"We are very proud of this new agreement, that demonstrates ASFC's strong confidence in our therapeutic program" says Manuel GEA CEO of BMSystems.

**A clear and operational therapeutic response to ME/CFS and the related Post Covid-19 Syndrome.
Keep in mind that ME/CFS most often starts as post viral syndrome.**

It is clearly documented that the current coronavirus epidemic, caused by the ssRNA SARS-CoV-2 virus, is likely to trigger a worldwide ME/CFS spike. A proportion of the exposed population may go on to develop ME/CFS in the medium term.

The mechanisms described by BMSystems explain a two-step triggering process, which leads to a dysfunction of the immune system, characteristic of a post-viral ME/CFS syndrome.

It turns out that Covid-19 infection may play the role of trigger number 2.

"After many decades of little progress from medical research, our association must do everything possible to support the development of BMSystem's innovative solution, a hope for improving the lives of all ME/CFS patients, whose number is only likely to grow as the after-effects of Covid-19 become apparent." explains Robert Schenk, President of the ASFC;

A major shift for the recognition of the disease:

CADI-T1031 is a therapeutic solution based on a "disease-centric repositioning of existing molecules". **This discovery transforms ME/CFS from a syndrome that lacks concrete diagnostic criteria and treatment into a universally recognizable, diagnosable and treatable organic disease.**

Post-Covid-19 Syndrome and ME/CFS spike:

BMSystems' research has shown that ME/CFS is an inflammatory disease, caused by overlapping immune responses that misguide the actions of the immune system. When this occurs, the immune system tries to resolve simultaneously infection-like hazards that require opposing and often mutually-cancelling strategies (known as humoral and cellular responses). The result is the immune system getting 'stuck' in a constant, low-potency, pro-inflammatory mode with the physical manifestation of

CFS/ME symptoms. One of the triggers for such responses are acute infections with positive sense ssRNA viruses such as coronaviruses.

As also Anthony Fauci, the U.S. infectious diseases leading expert, acknowledged, the symptoms in many of Post-Covid-19 unrecovered patients are “highly suggestive” of ME/CFS.

The development programme is under the shared leadership of **Dr Isabelle Fornasieri**, Scientific Coordinator to the ASFC, **Dr. François Iris**, founder and CSO, **Thanos Beopoulos** Integrative Biology Director, and **Dr Gerard Dine** CMO of Bio-Modeling Systems.

About ME/CFS:

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome remains a debilitating condition for the patient and a confusing one to doctors, both because of diagnostic difficulties and poorly codified management. Despite numerous studies, its pathophysiology remains unclear, but a multifactorial origin is suspected with triggering (infections) and maintenance factors as well as the persistence of inflammatory (low-grade inflammation, microglial activation...), immunologic (decrease of NK cells, abnormal cytokine production, reactivity to a variety of allergens, role of estrogens...) and muscular (mitochondrial dysfunction and failure of bioenergetic performance) abnormalities. Such factors are at the origin of multiple dysfunctions (endocrine, neuromuscular, cardiovascular, digestive...). The frequency of ME/CFS depends on the criteria of definition, with prevalence between 0.2 and 2.6% in Western countries. The ratio of women to men is about 3/1, with predominance in young adults (20-40 years) but a possible attack can come at any age and genetic predisposition. Between 836,000 and 2.5 million Americans and between 150,000 and 300,000 people in France would suffer with sometimes severe degrees of disability generating high health costs.

About Bio-Modeling Systems (BMSystems):

Bio-Modeling Systems, an innovative company founded in 2004, is the first and, to date, only company to successfully create in-silico heuristic models validated in-vivo. BMSystems' heuristic models, built by its biologists using an integrated IT solution called CADI™ (Computer Assisted Deductive Integration) have led to discoveries and patents in the fields of infectious diseases, oncology, neurology, psychiatry, dermatology, immunology, metabolic disorders, innovative bioprocesses for industrial biotech and the creation of new companies exploiting these patents. BMSystems' models describe the biological phenomena involved in pathological states and provide novel mechanistic integrations to explain the cause of certain diseases, identify and select predictive biomarkers, and offer new combinations of molecules and new therapeutic strategies.

Already, two of BMSystems R&D programs led to the creation of pharmaceutical start-ups that are now in the clinical stage:

1. **Pherecydes-Pharma (2006): First BMSystems' therapeutic spin-off**, (novel M.R. anti-bacterial nano-agents biotherapies with phages), indications: Multi-resistant infections compassionate use success.
2. **CEA/BMSystems collaborative research in the Central Nervous System** (psychiatric and neurological disorders) led to the **co-owned patent WO201029131** with a **worldwide exclusive license** to a **CEA's spin-off**.

For more information and access to presentations & publications, please visit <https://www.bmsystems.org>

About the French Chronic Fatigue Syndrome Association (ASFC):

ASFC is the only association approved by the French Ministry of Health that represents patients with ME/CFS. The association provides a phone hotline and organizes regular meetings between patients and volunteers everywhere in France, as well as meetings and live webinars with expert scientists. The ASFC welcomes everyone suffering from unexplained chronic fatigue, post-viral fatigue syndrome, and ME/CFS, and informs and guides them to obtain an accurate diagnosis. The ASFC also promotes

research protocols (scientific, medical or multidisciplinary) and is engaged in awareness-raising in order to influence government strategy for recognition of ME/CFS in France.

One of the challenges of the partnership will be to aggregate a network of care-givers in Europe, around this mechanism-based medicine project for ME/CFS.

President of ASFC: Mr. Robert Schenk

Scientific Coordinator of ASFC: Isabelle Fornasieri (PhD)

For more information, please visit <http://www.asso-sfc.org>

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