

## INDENA IS THE FIRST COMPANY IN ITALY AUTHORISED TO PRODUCE CBD

### LEADING BOTANICAL EXTRACTS COMPANY TO PRODUCE PHARMACEUTICAL GRADE CBD FOR THE INTERNATIONAL MARKET, USING ITALIAN BIOMASS

Milan, 1<sup>st</sup> March 2021 - Indena, a leading Italian company in international markets, has been authorised by the Italian Ministry of Health and Italian Medicines Agency (AIFA) to produce cannabinoid-based cannabis extracts. Indena will produce pharmaceutical grade cannabidiol (CBD) for the global market for clinical and commercial use.

Indena is the first company in Italy to receive authorisation from the Ministry of Health to manufacture cannabinoid-based cannabis extracts. The approval process continued and Indena has also received authorisation from the AIFA, making it one of the few companies in the world able to produce cannabidiol (CBD) for the pharmaceutical market. CBD is an active ingredient obtained by extraction and isolation from the inflorescences and aerial parts of hemp (*Cannabis sativa* L.).

With its 100 years of experience in the production of high-end botanical extracts, Indena is well placed to produce high purity CBD. The raw material will be grown and processed in Italy. The supply chain, which complies with the strict criteria set out in the Italian regulations, is controlled, certified and fully traced by the company. Indena's traditional rigour in managing the production chain was a key factor in obtaining authorisation.

Indena uses registered varieties of hemp with a THC level of less than 0.2% in accordance with European standards. It also guarantees a residual THC content of less than 0.02%, well below the limits defined by the FDA (Food and Drug Administration) and by DEA (Drug Enforcement Administration). This approach enabled Indena to promptly submit the DMF (Drug Master File) for this product to the FDA.

*"We have been working a long time for this outcome. It is the result of an intense and fruitful collaboration with the Ministry of Health and the AIFA, for the construction of a rigorous approval process to guarantee the safety and control of production, both of the raw material and of the active principle", says **Stefano Togni, Corporate Director for Business Development and Licensing of Indena SpA.** "We are aiming at the international pharmaceutical markets. As an Italian company, we are proud to be able to make this totally Italian product of the highest quality available globally, an ingredient expected all over the world for its beneficial effects on a number of pathologies".*

The hemp biomass used by Indena is processed in a pharmaceutical plant that is regularly authorised by AIFA and inspected by the main international regulatory agencies (FDA, KFDA, PMDA and others). All production is carried out in compliance with pharmaceutical GMP (Good Manufacturing Practices), in line with the highest quality standards that the company has always applied which have been recognised by the international scientific community and consolidated over 100 years of business.

Cannabidiol (CBD) is an active pharmaceutical ingredient whose use is approved for seizures associated with some rare forms of childhood epilepsy (Lennox-Gastaud syndrome, Dravet syndrome and tuberous sclerosis complex), and in clinical development for other forms of epilepsy. Furthermore CBD is under clinical investigation for schizophrenia, and for its therapeutic potential in other psychiatric disorders, neurological or autoimmune/inflammatory based diseases<sup>1</sup>.

Once again, Indena's focus on quality, scientific rigour and innovation has enabled it to receive recognition from Italy's top pharmaceutical regulatory institutions. This will enable the company to produce an active principle for which there has been market demand for some time.

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1. C. Michael White, PharmD, A Review of Human Studies Assessing Cannabidiol's (CBD) Therapeutic Actions and Potential, J Clin Pharmacol 2019, 59(7), 923-934.



**Indena** is the leading company dedicated to the identification, development and production of high quality active principles derived from plants, for use in the pharmaceutical and health food industries. Backed up by a century of botanical experience, the company owns 100 patent families, has published more than 1000 scientific studies and cooperates with the world's most prestigious universities and private research institutions. Indena employs over 900 staff, investing a significant amount of its annual turnover in research, making this activity the key to its success. Headquartered in Milan, Indena has 4 production sites and 5 international branches throughout the world and manages sales in more than 80 countries. The company's experts communicate and interact constantly with the major international regulatory authorities and cooperate on the update of all the main pharmacopoeias.

Today Indena has further expanded its CDMO offer encompassing new services. In particular, a kilolab to handle semisynthetic and total synthetic APIs that require high containment (OEL of 20 ng/m<sup>3</sup>), a new multipurpose GMP pilot plant, a multipurpose fermentation suite and large-and-mid size spray dryers working with organic solvents. Find more on [indena.com](http://indena.com)

#### **Indena press contacts**

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