

Encouraging results of GuidAge[®], large scale European trial conducted in the prevention of Alzheimer's Dementia

- Primary efficacy objective (to delay conversion to Alzheimer's Dementia):
 Unmet in overall study population
 - Met in patients treated for a duration of at least 4 years
- The GuidAge[®] study marks a milestone for future research on Alzheimer's Disease and for prevention strategies
- Ipsen intends to transfer a unique biobank to French Academic research

Paris (France), 22 June 2010 - Ipsen (Euronext: IPN; ADR: IPSEY) today announced top line results of GuidAge[®], the longest (5 years) and largest (2,854 subjects) European study in the prevention of Alzheimer's Dementia (AD). This trial was conducted according to the most stringent international standards. The aim of this study was to assess the efficacy of a 5-year treatment with EGb 761[®] in the prevention of Alzheimer's Dementia in a population of elderly aged 70 or more, with memory complaint spontaneously expressed to their family physician and who lived at home at the inclusion in the study.

1. Primary efficacy objective (to delay conversion to Alzheimer's Dementia): significant difference not statistically observed in the overall study population: during the study, 134 individuals developed Alzheimer's Dementia, including 61 patients (4.3%) in the EGb 761[®] group and 73 patients (5.2%) in the placebo group (p=0.31). However, a statistically significant difference between EGb 761[®] and placebo was observed in patients treated for a least 4 years: pre-specified planned statistical analyses suggest a difference in favour of EGb 761[®] versus placebo on the conversion to Alzheimer's Dementia in patients treated for at least 4 years: 15 out of 947 patients (1.6%) in the EGb 761[®] group with treatment duration of at least 4 years converted to Alzheimer's dementia versus 29 out of 966 (3.0%) in the placebo group (statistically

significant at p=0.03). These analyses suggest as well a statistically significant difference in favour of EGb 761[®] in males: 14 out of 480 males (2.9%) in the EGb 761[®] group converted to AD versus 32 out of 460 (7.0%) in the placebo group (statistically significant at p=0.007).

Complementary analyses will enable to further investigate these differences.

EGb 761[®]'s favourable long-term safety profile was monitored and confirmed.

2. GuidAge[®] study marks a milestone for future research on Alzheimer's Disease and for prevention strategies

Beyond clinical results, this major trial, which involved a total population of 2,854 patients at risk of developing Alzheimer's Disease, will provide large opportunities for further investigation by the scientific and medical communities. In particular, new perspectives were opened by the study:

- Forthcoming analyses of GuidAge[®] results to identify the transition from subjective memory complaint to cognitive decline and dementia up to 5 years.



- Leverage of Alzheimer's disease research through the transfer from Ipsen to French academic research of a biobank constituted along the GuidAge[®] trial and containing blood samples and DNA extraction from 2,107 patients.

GuidAge[®] is therefore one of the main scientific contribution to neurodegenerative research in line with the French Government's strategy of fostering research and prevention in Alzheimer's dementia.

Pr. Bruno Vellas, Principal Investigator of the study, INSERM U558, Gérontopôle (Toulouse, France), said: "The specific characteristics of GuidAge[®] study are on the one hand the target population (subjects aged of at least 70 with memory complaint spontaneously expressed to their family physician), and on the second hand, the cooperation between memory clinics and a network of 658 family physicians trained in clinical research, probably responsible for the noticeable compliance in 93 % of the intention-to-treat population. The results of this clinical trial, which will have to be investigated in further studies, are encouraging and open new perspectives."

Dr. Patrick Mérat, Senior Vice-President, Drug Development and Chief Medical Officer,

Ipsen, said: "Ipsen is proud to have carried out the largest and longest European study in the prevention of Alzheimer's Dementia, thus contributing to a public health priority. We would like to express our gratitude to the renowned scientific and independent data monitoring committees as well as to the investigators and patients involved in the study. Ipsen is determined to pursue its long term commitment with academic investigators to advance knowledge in Alzheimer's disease by its intent to transfer GuidAge[®] remarkable biological bank to French academic research. This biobank will represent a valuable source of knowledge in the Alzheimer's Disease area. Within the context of these results, it is Ipsen's intention to assess all the potential strategies so as to carry these findings further."

About EGb 761[®]

EGb 761[®], which is the active substance of Tanakan[®], is a unique standardized extract of Ginkgo biloba. This compound features antioxidant and neuroprotective property as well as an action on β -amyloid protein in experimental models. Its consistent composition in pharmacologically active substances is achieved through specially designed plantations of Ginkgo biloba (dioecious tree in the Ginkgoaceae family) that are cultivated under controlled conditions and a standardised extraction and purification process. EGb 761[®] is indicated and registered in many countries for the treatment of cognitive disorders in the elderly as well as neurosensory disorders.

About GuidAge[®]

The aim of the GuidAge[®] study was to assess the efficacy of EGb 761[®] at a dose of 240 mg daily in the prevention of Alzheimer's Dementia (AD) in a population of subjects aged 70 or more with a memory complaint spontaneously expressed to their family physician and living at home at the inclusion. GuidAge[®] is the longest and largest European study in this disease and has been conducted in full compliance with the most stringent international standards. GuidAge[®] was a 5-year double-blind randomized trial versus placebo conducted in France by a network of family physicians and memory clinics. The primary endpoint was the incidence of AD during a 5-year follow-up period. A total of 2,854 subjects were enrolled between March 2002 and November 2004. At entry, the mean age of the study population was 76.3 (± 4.4), with mean MMSE (Mini Mental State Evaluation) at entry of 27.6 (± 1.9). Last patient last treatment date was November 2009.

The outcomes of the study pointed out that 134 individuals developed dementia of Alzheimer's type, including 61 patients (4.3%) in the EGb 761[®] group and 73 patients (5.2%)



in the placebo group; this difference was not significant (p=0.31). Global conversion rate found in the placebo group (5.2%) was 50% lower than usually reported in the general French population. In planned pre-specified analysis, results were in favour of EGb 761[®] in patients treated for at least 4 years (1.6% versus 3.0% in the placebo group, p=0.03) and in males (2.9% versus 7.0% in the placebo group, p=0.007).

Both the dose and indication in the GuidAge[®] study are not approved by regulatory authorities.

About lpsen's involvement in neurology

Ipsen has developed specialized expertise in the treatment of neuromuscular disorders and neurodegenerative diseases. The Group currently market Dysport[®] which is mainly used in the symptomatic treatment of spasticity, cervical dystonia and blepharospasm, as well as Apokyn[®] for the treatment of "off" episodes (re-emergence of Parkinson's disease symptoms) associated with advanced Parkinson's disease in the United states. Whereas Ipsen's research in neurology mainly focus on the development of new botulinum toxin formulations, Ipsen has synthetized several classes of chimeric compounds in neurodegenerative conditions such as Parkinson's and Huntington's diseases or amyotrophic lateral sclerosis.

About Ipsen

Ipsen is a global biopharmaceutical group with total sales in excess of 1 billion euros in 2009, and total worldwide staff of more than 4,400. Its strategy is based on fast growing specialty care drugs in oncology, endocrinology, neurology and hematology, and primary care drugs, which significantly contribute to research financing. This strategy is also supported by an active policy of partnerships. Ipsen's specific Research & Development (R&D) centers and peptide & protein engineering platform give the Group a competitive edge. Nearly 900 people are dedicated to the discovery and development of innovative drugs for patient care. Nearly 900 people are dedicated to the discovery and development of innovative drugs for patient care. In 2009, R&D spend reached close to €200 million, representing more than 19% of total Group sales. Ipsen's shares are traded on Segment A of Euronext Paris (stock code: IPN, ISIN code: FR0010259150). Ipsen's shares are eligible to the "Service de Règlement Différé" ("SRD") and the Group is part of the SBF 120 index. Ipsen has implemented a Sponsored Level I American Depositary Receipt (ADR) program, which trade on the over-the-counter market in the United States under the symbol IPSEY. For more information on Ipsen, visit our website at <u>www.ipsen.com</u>.

Forward Looking Statement

The forward-looking statements, objectives and targets contained herein are based on the Group's management strategy, current views and assumptions. Such statements involve known and unknown risks and uncertainties that may cause actual results, performance or events to differ materially from those anticipated herein. Moreover, the targets described in this document were prepared without taking into account external growth assumptions and potential future acquisitions, which may alter these parameters. These objectives are based on data and assumptions regarded as reasonable by the Group. These targets depend on conditions or facts likely to happen in the future, and not exclusively on historical data. Notably, future currency fluctuations may negatively impact the profitability of the Group and its ability to reach its objectives. Actual results may depart significantly from these targets given the occurrence of certain risks and uncertainties. The Group does not commit nor gives any guarantee that it will meet the targets mentioned above. Furthermore, the Research and Development process involves several stages each of which involve the substantial risk that the Group may fail to achieve its objectives and be forced to abandon its efforts with regards to a product in which it has invested significant sums. Therefore, the Group cannot be certain that favourable results obtained during pre-clinical trials will be confirmed subsequently during clinical trials, or that the results of clinical trials will be sufficient to demonstrate the safe and effective nature of the product concerned. The Group also depends on third parties to develop and market some of its products which could potentially generate substantial royalties; these partners could behave in such ways which could cause damage to the Group's activities and financial results. The Group expressly disclaims any obligation or undertaking to update or revise any forward looking statements, targets or estimates contained in this press release to reflect any change in events, conditions, assumptions or circumstances on which any such statements are based, unless so required by applicable law. The



Group's business is subject to the risk factors outlined in its registration documents filed with the French Autorité des Marchés Financiers.

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