

Lilly's Commitment to Alzheimer's R&D

Since Dr. Alois Alzheimer first identified Alzheimer's disease in 1906, Alzheimer's disease has confounded researchers across the globe and devastated many families. Yet, more than a century later, there is still no cure or effective way to prevent or slow this disease. Here we tell the story of Lilly's 30 year, 3 billion USD journey in seeking to discover a medicine to help combat Alzheimer's disease, and the importance of incentivizing ongoing research efforts to help the patients of today, and tomorrow.

As Europeans get older and life expectancy increases, there has been a dramatic rise in the prevalence and impact of diseases associated with aging including dementia. **Alzheimer's disease is the most common form of dementia**, accounting for 60 to 80% of cases. In EU Member States alone, around 9.6 million people are living with Alzheimer's disease, equivalent to nearly one in every 50 people¹. The current **annual societal and economic cost of dementia in Europe is estimated at 275 billion EUR²**.

Globally, there are currently an estimated 47 million people living with dementia. **This is set to increase to nearly 75 million by 2030** and 131 million by 2050³. Almost 10 million new cases of dementia are diagnosed each year worldwide.

Drug discovery in pursuit of this disease has a turbulent past, and **there is still no cure, or effective treatment that slows the progression of Alzheimer's disease**. A 2014 study looked at clinical trial success rates for Alzheimer's disease treatments between 2002 and 2012⁴. Of a total of 244 compounds, only one was approved – a medicine that treats symptoms, but does not slow the progression of Alzheimer's disease. The report points out that this gives **Alzheimer's disease drug candidates one of the highest failures rates of any disease area – 99.6%**, compared with 81% for cancer.

Lilly's 30 year journey

Lilly has been conducting Alzheimer's research for nearly 30 years and is deeply committed to finding approaches that modify the course of the disease and make Alzheimer's dementia preventable. A recent example of the inherent and significant challenges of research and development in this field is the investigational Alzheimer's disease treatment solanezumab, a monoclonal antibody Lilly studied for the treatment of dementia due to Alzheimer's disease in certain patient populations. Results from Phase 3 clinical studies of solanezumab revealed that patients treated with solanezumab did not experience a statistically significant slowing in cognitive decline compared to patients treated with a placebo. **In total, Lilly's effort to research solanezumab spanned more than a decade**. This development programme required the involvement of several hundred employees with deep R&D expertise and more than 4,000 patients globally, costing several hundred million dollars. In Europe patients from France, Germany, Italy, Poland, Spain, Sweden and the United Kingdom were enrolled in the study, with numerous European clinical researchers leading the research.

Overall, **Lilly has invested more than 3 billion USD** in the quest to develop an effective treatment for the disease without a single approved treatment to date. If solanezumab had been successful in meeting its study goals, it would have been the first treatment to slow the progression of Alzheimer's disease. But even in its "failure", **the knowledge gained from these studies may be valuable to future development efforts** by academia, government and innovative companies. While R&D efforts may not result in a therapeutic treatment the knowledge gleaned from these research efforts can move the entire field forward.

60-80%
of dementia cases
are Alzheimer's

10 million
new cases of
dementia per year
worldwide

99.6%
drug failure rate

3 billion USD
invested by Lilly
to develop an
effective treatment

25% of
Lilly's revenues
are re-invested
back into R&D



#WeWontRest

until we find ways to modify the course of Alzheimer's.

For nearly 30 years,
Lilly has committed to Alzheimer's R&D
and we're not slowing down.
Our dedication is stronger than ever.

Michael Hutton
UK
CSO, Neurogeneration
Lilly



A reliable incentives framework is needed for research to continue

To enable continued research efforts in such high unmet medical need diseases like Alzheimer's, a predictable and reliable system that incentivises investment into high risk research areas has to be provided.

When a team of researchers spends decades developing potential new treatments in the face of uncertainty and setbacks, we need to ensure their innovation is encouraged and recognized – driving forward the next frontier of research. **The path from basic research to new medicines is extremely complex in any disease area, but particularly so in Alzheimer's disease.** Unfortunately, in a research field fraught with scientific uncertainty and risk such as Alzheimer's disease, there is always concern that research, including the resources to foster it, may start to dissipate, potentially slowing the path for a cure or disease-modifying treatment.

Intellectual Property (IP) is the most important spoke in our investment wheel; it is the life blood of our industry.

The pharmaceutical incentives regime is a key driver to stimulate research and the development of new innovations, and to protect a new product brought to the market against unfair competition for a limited period of time.

Lilly re-invests almost 25% of revenues back into R&D, a figure enabled through a predictable and strong pharmaceutical incentives and reward system. The matrix of IP incentives possibly available for a new medicine allowed Lilly to continue performing this critical research, for an extended period, involving substantial resources.

The overwhelming lack of success in research to effectively treat, slow or cure Alzheimer's disease to date reinforces the value of the existing pharmaceutical incentives regime in encouraging the ongoing cycle of innovation by the industry to help the millions of people living with the disease and the loved ones who care for them.

- 1 Health at a glance 2016: Europe. World Health Organisation: http://www.keepeek.com/Digital-Asset-Management/oe.cd/social-issues-migration-health/health-at-a-glance-europe-2016_9789264265592-en#page19
- 2 World Alzheimer Report 2015: The Global Impact of Dementia. Alzheimer's Disease International. <https://www.alz.co.uk/research/WorldAlzheimerReport2015.pdf>
- 3 Dementia statistics. Alzheimer's Disease International. <http://www.alz.co.uk/research/statistics>. Accessed October 2016.

- 4 Alzheimer's disease drug-development pipeline: few candidates, frequent failures
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Lilly in Europe

Lilly was founded over 140 years ago and has been at the forefront of numerous medical breakthroughs that have improved life for millions of people. Lilly's internal research efforts are primarily focused on the following therapeutic areas: oncology, diabetes, pain, immunology and neurodegeneration.



For more information please contact:

Doris Schernhammer
Associate Director, Corporate Affairs Europe
schernhammer_doris@lilly.com



www.lilly-europe.eu
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[@lillypadeu](https://twitter.com/lillypadeu)