Lars J. S. Knutsen, Ph.D.

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PROFILE

Results-driven **Pharma R&D Consultant, Drug Discovery Director** and **Senior Medicinal Chemist**. Expert in design and selection of Drug Candidates; broad neuroscience medicinal chemistry capability focused on treatments for epilepsy, sleep disorders, cognition and neurodegeneration. Motivated teams of scientists to achieve goals in 6 companies over a 30+ year Pharma/Biotech career. Superb analytical skills and deep pharma industry knowledge. Closely involved in 7 NCEs of which 5 progressed to clinical trials, including Vipadenant (Parkinson's Disease) and Irdabisant (Cognition); anticonvulsant Gabitril™ marketed worldwide.

Adjunct Professor at Drexel University School of Medicine since 2009; regular major conference speaker with 45 peer-reviewed publications, 33 published PCT patents; 22 issued in US. **Chaired Patent Committees** at **Ionix Pharma** and **Vernalis PLC**; strong knowledge of Pharma patenting process in US and EU with its many issues. Member of NIMH/NCDDDG NIH Grant Review Panel, 2010 and 2011. Articulate and creative scientific leader with excellent interpersonal skills; methodical and focused. Peer recognized high-level heterocyclic, nucleoside and carbohydrate chemist with in depth knowledge of organic chemistry. Drug biology and PK/ ADME knowledge, Fellow, Royal Society of Chemistry, ACS and SfN member; became a US Citizen in 2015.

PROFESSIONAL EXPERIENCE

Discovery Pharma Consulting LLC. West Chester, PA USA **Feb. 2009 - present**
President
Founded as Lars' 4th start-up in response to clients requesting expert Pharma R&D Consulting services. Specializing in IP Expert Witness work, Preclinical Drug Discovery; including Hit-to-Lead, Lead Optimization and Preclinical Development phases. Medicinal Chemistry input provided along with Strategic IP and R&D Portfolio reviews, see www.discoverypharm.com. Some assets have been transitioned into a new product-focused Biotech focused on drugs for sleep and CNS disorders, Requis Pharma Inc., where I am Acting CEO.

Drexel University College of Medicine Philadelphia, PA **November 2009 - present**
Adjunct Professor
Appointed by Prof. James Barrett, Dept. of Pharmacology and Physiology, to advise and collaborate with faculty on drug R&D strategy, to teach Drug Discovery, and to drive entrepreneurism in the wider Drexel community.

Charcot-Marie Tooth Association **May 2013 - present**
Science Advisory Board and Therapy Expert Board Member, researching treatments for CMT disease, an inherited peripheral neuropathy, in the non-profit CMTA: http://www.cmtausa.org/research/star-advisory-board/

Cephalon, Inc. West Chester, PA USA **2005 - 2008**
Distinguished Scientist/ Project Leader
Hired into this newly-created role, built new team; drove initiation of and managed new Schizophrenia project. Key input to strategic course of Cephalon R&D in Oncology and CNS in Project Management Group.

- Major contributor to Cognition program – invented Irdabisant (CEP-26401), my 5th career NCE and Cephalon's most recent clinical drug: https://www.clinicaltrials.gov/ct2/show/NCT01903824?term=irdabisant&rank=1
- Synthesis lab. presence with high compound output; drove several projects with external chemistry CROs.
- Cephalon's first Distinguished Scientist; consulted internally on the anticonvulsant Gabitril™, a Cephalon product

Ionix Pharmaceuticals Cambridge, UK **2001 – 2005**
Director of Chemistry
Responsible for R & D Chemistry, including strategy/ budgeting, in this pain and ion-channel focused start-up company. Built outstanding team of 15+ medicinal chemists and computational chemist. Key member of Ionix Management Team, Product Management Group and Chair of Intellectual Property Strategy Meeting.

- Drove creative medicinal chemistry/parallel synthesis in calcium and sodium channel blocker projects. Project

Vernalis (formerly Cerebrus), Wokingham, UK **1997 – 2001**
Associate Director, Medicinal Chemistry

- Initiated Discovery project for new adenosine A_{2A} antagonists for Parkinson's Disease; Vipadenant (VR 2006) showed PoC, made it to Phase II in Biogen Idec, see: http://production.investis.com/ver/rdc/v2006/?t=print
- Leader of Sodium Channel program; Head of Pre-Project group; involved in Autism research.
- Started pre-project targeting novel CB_1 antagonists in 2001; lead compound, V24343, entered clinical trials for obesity late in 2006, see: http://www.vernalis.com/media-centre/archive-releases/2006-releases/407
- Recruited and coached 5 medicinal chemists to join my team as direct reports.
- Member of Chemistry Management Team, devised company strategies for I.P. and Parallel Synthesis.
- Part of Integration Team following Vanguard merger with Cerebrus in late 1999.

Novo Nordisk, Pharmaceuticals Division, Måløv, Denmark **1993 – 1997**
Principal Scientist and Department Leader, Medicinal Chemistry

- Project Manager, Purine project group; initiated project on adenosine A_1 receptor agonists for stroke. Led high-performing team of chemists. Promoted to Department Head in 1995.
- A_1 agonist drug candidate NNC 21-0136, selected as pre-clinical compound 2¼ years from project start; back-up NNC 21-0149 also identified. Completed Novo management/ project manager training modules
- Gabitril™ launched as novel anticonvulsant in 1997; Invented back-up series to Gabitril, NNC-711 – authored 1999 *J. Med. Chem.* article. NNC-711 reviewed in CNS Drug Reviews, **1999**, *5*, 317-330.

Novo Industri CNS Division, Copenhagen, Denmark **1986 - 1993**
Project Leader/ Senior Chemist

- Project Manager, GABA Uptake III project group. Promoted to Principal Scientist in 1993.
- Led project team driving discovery & selection of the marketed anticonvulsant Tiagabine (Gabitril™).
- Principal author of 1993 *J. Med. Chem.* describing synthesis, SAR of Gabitril, as well as back-ups in 1999.

Glaxo Group Research, Ware, Herts. UK **1978 - 1986**
Research Chemist in Medicinal Chemistry

- Drove forward design and synthesis of novel nucleoside antiviral agents, acyclovir analogues and adenosine receptor ligands in this entry-level role; promoted to S2 chemist after 1 year.
- Completed Ph.D. studies externally through King's College, London while at Glaxo.

AWARDS AND HONORS

- Appointed to the Science Advisory Board of the Charcot Marie Tooth Association (2013)
- Awarded prize as top 10 reviewer for Bioorganic and Medicinal Chemistry Letters (2012)
- Appointed as an adjunct Professor at Drexel University College of Medicine (2009)
- Honored at dinner for the 2 Cephalon Distinguished Scientists; portrait placed in foyer of R&D HQ (2007)
- Awarded O-1 Outstanding Expert ("Rock Star") Visa to the US (2005), became US Citizen (2015)
- Appointed as a Fellow of the Royal Society of Chemistry (1999)

EDUCATION

Ph.D. in **Medicinal Chemistry** (while employed at Glaxo, Ware, Herts, UK) in collaboration with Prof. C.B. Reese, Kings College, London & CNAA). Ph.D. thesis: "The Synthesis of Bridgehead Nitrogen *C*-Nucleosides" yielded 7 major peer-reviewed publications. Advisors: Prof. Roger F. Newton & Dr. David I.C. Scopes.
B.A. (Hons.)/ M.A. in Chemistry 1978, Christ Church, University of Oxford

JOURNAL INVOLVEMENT & COLLABORATIONS

- Served on Editorial Advisory Board of Drug Development Research (1994 – 2010) and a regular reviewer for *J. Med. Chem.* and *Bioorg. Med. Chem. Lett*.
- Initiated collaborations with academic groups, with *e.g.* Dr. Ken Jacobson (NIH, USA), Prof. Joel Linden (Univ. of Virginia, Charlottesville, USA) and Prof. Stan Roberts, (Univ. of Liverpool, U.K.). When at Novo Nordisk, supervised 4 successive postgrad. students in Medicinal Chemistry with Prof. Roberts, 2 to successful Ph.D. and 2 to M.S. The students worked both in my lab. at Novo Nordisk and at Prof. Roberts' Dept. Funding provided by the Novo Nordisk Foundation;

PUBLICATIONS

1. Knutsen, L.J.S.; Aimone, L.D.; Bacon, E.R.; Lyons, J.; Prouty, C.P.; Raddatz, R.; Sundar, B. and Hudkins, R.L. **3,6-Disubstituted Pyridazines as Novel Analogues of CEP-26401: CNS Penetrant Histamine H_3 Receptor Antagonists.** *Bioorg. Med. Chem. Lett.*, manuscript submitted.

2. Hudkins, R.L.; Raddatz, R.; Tao, M.; Mathiasen, J.R..; Aimone, L.D.; Becknell, N.C.; Prouty, C.P.;. Knutsen, L.J.S.; Yazdanian, M.; Moachon, G.; Ator, M.A.; Mallamo, J.P.; Marino, M.J.; Bacon, E.R. and Williams, M. **Discovery and Characterization of 6-{4-[3-(R)-2-Methylpyrrolidin-1-yl)prop-oxy]phenyl}-2H-pyridazin-3-one (CEP-26401, Irdabisant): A Potent, Selective Histamine H_3 Receptor Inverse Agonist**. *J. Med. Chem*., **2011**, *54*, 4781-4792.

3. Knutsen, L.J.S. **Drug discovery management, small is still beautiful: Why a number of companies get it wrong**. *Drug Discovery Today*, **2011**, *16*, 476-484.

4. Gillespie, R.J.; Adams, D.R.; Bebbington, D.; Benwell, K.; Cliffe, I.A.; Dawson, C.E.; Dourish, C.T.; Fletcher, A.; Gaur, S; Giles, P.R.; Jordan, A.M.; Knight, A.R.; Knutsen, L.J.S.; Lawrence, A.; Lerpiniere, J.; Misra, A.; Porter, R.H.P.; Pratt, R.M.; Shepherd, R. Upton, R.; Ward, S.E.; Weiss, S.M. and Williamson. D.S. **Antagonists of the human adenosine A_{2A} receptor. Part 1: Discovery and synthesis of thieno[3,2-d]pyrimidine-4-methanone derivatives**. *Bioorg. Med. Chem. Lett.*, **2008**, *18*, 2916 - 2919.

5. Marino, M.J.: Knutsen, L.J.S and Williams M. **Perspective: Emerging Opportunities for Antipsychotic Drug Discovery in the Postgenomic Era** *J. Med. Chem*., **2008**, *51*, 1077 - 1107.

6. Knutsen, L.J.S., Hobbs, C.J.; Earnshaw, C.G., Fiumana, A., Gilbert, J., Mellor, S.L., Radford, F., Smith, N.J., Birch, P.J., Burley, R., Thomas, D., Ward, S.D.C. and James, I.F. **Synthesis and SAR of novel 2-arylthiazolidinones as selective analgesic N-type calcium channel blockers**. *Bioorg. Med. Chem. Lett.*, **2007**, *17*, 662 - 667.

7. Marino, M.J.: Davis, R.E.; Meltzer, H.E.; Knutsen, L.J.S and Williams M. **Schizophrenia**. In *Comprehensive Medicinal Chemistry* II (Taylor, J.B; Triggle, D. J., Editors-in-Chief) Vol. 6; Therapeutic Areas I (M. Williams, Volume Editor), **2006**, pp. 17 - 44.

8. Knutsen, L.J.S and Williams M. **Epilepsy**. In *Comprehensive Medicinal Chemistry* II (Taylor, J.B; Triggle, D. J., Editors-in-Chief) Vol. 6; Therapeutic Areas I (M. Williams, Volume Editor), **2006**, pp 279 - 296.

9. Bowdle, T. A., Knutsen, L.J.S and Williams M. **Local and Adjunct Anesthesia**. In *Comprehensive Medicinal Chemistry* II (Taylor, J.B; Triggle, D. J., Editors-in-Chief) Vol. 6; Therapeutic Areas I (M. Williams, Volume Editor), **2006**, pp 351 - 368.

10. Haldeman, M.; Vieira, B.; Winer, F. and Knutsen, L.J.S. **Exploration Tools for Drug Discovery and Beyond: Applying SciFinder® to Interdisciplinary Research**. *Current Drug Discovery Technologies*, **2005**, *2*, 69 - 74.

11. Knutsen, L.J.S.; Weiss, S.M; **KW-6002, Kyowa Hakko Kogyo.** *Curr. Opin. Invest. Drugs* (PharmaPress Ltd.), **2001**, *2*, 668 - 673.

12. Jacobson, K.A. and Knutsen, L.J.S.; **P1 and P2 Purine and Pyrimidine Receptor Ligands**. In *Handbook of Experimental Pharmacology, Volume 151/I: Purinergic and Pyrimidinergic Signalling I;* Abbracchio M.P. and Williams, M., Eds.; Springer-Verlag: Berlin, Germany; 2001, pp 129 - 175.

13. Bentley, J.M., Cliffe, I.A., Knutsen, L.J.S., Monck, N.J. **Medicinal Chemistry – 16th International Symposium**, *I Drugs*, **2000**, *3*, 1457 – 1486.

14. Dhanda, A.; Knutsen, L.J.S.; Nielsen, M-B; Roberts, S.M.; Varley, D.R. **Facile conversion of 4-endo-**

15. Cliffe, I.A., Bebbington, D., Gillespie, R.J. and Knutsen, L.J.S. **RSC-SCI Tenth Medicinal Chemistry Symposium**, *I Drugs*, **1999**, Week 38, 25 - 29.

16. Andersen, K.E; Sorensen, J.L.; Huusfeldt, PO.; Knutsen, L.J.S.; Lau, J.; Lundt, B.F.; Petersen, H.; Suzdak, P.D.; Swedberg, M.D.B. **Synthesis of Novel GABA Uptake Inhibitors. 4. Bioisosteric Transformation and Successive Optimization of Known GABA Uptake Inhibitors Leading to a Series of Potent Anticonvulsant Drug Candidates**. *J. Med. Chem*., **1999**, *42*, 4281 - 4291.

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18. Knutsen, L.J.S., Andersen, K.E., Lau, J., Lundt, B.F., Henry, R.F., Morton, H.E., Nærum, L., Petersen, H., Stephensen, H., Suzdak, P.D., Swedberg, M.D.B., Thomsen, C. and Sørensen P.O. **The Synthesis of Novel GABA Uptake Inhibitors. 3. Diaryloxime and Diarylvinylether Derivatives of Nipecotic acid and Guvacine as Anticonvulsant Agents**. *J. Med. Chem*., **1999**, *42*, 3447 - 3462.

19. Knutsen L.J.S., Sheardown M.J., Roberts S.M., Mogensen J.P., Olsen U.B., Thomsen, C. and Bowler A.N. **Adenosine A_1 and A_3 Selective *N*-Alkoxypurines as novel Cytokine Modulators and Neuroprotectants** *Drug Dev. Res.* **1998**, *45*, 214 - 221.

20. Mogensen, J.P., Roberts, S.M., Bowler, A.N., Thomsen, C. and Knutsen, L.J.S.; **The Synthesis of New Adenosine A_3 Selective Ligands Containing Bioisosteric Isoxazoles**. *Bioorg. Med. Chem. Lett.* **1998**, *8*, 1767 - 1770.

21. Barkley, J.V., Dhanda, A., Knutsen, L.J.S., Nielsen, M-B., Roberts, S.M. and Varley, D.R. **Stereoselective Conversion of 2',3'-Dideoxydidehydrocarbocyclic nucleosides into 2'-Deoxycarbocyclic nucleosides**. *Chem. Commun*. **1998**, 1117 - 1118.

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33. Suzdak, P.D.; Frederiksen, K.; Andersen, K.E.; Soerensen, P.O.; Knutsen, L..J.S.; Nielsen, E.B. **NNC-711, a novel potent and selective γ-aminobutyric acid uptake inhibitor: pharmacological characterization.** *Eur. J. Pharmacol*., **1992**, *223*, 189 - 198.

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35. Knutsen, L.J.S.; **The Chemistry of 2'-deoxyribo-*C*-nucleosides**; *Nucleosides Nucleotides*, **1992**, *11*, 961 - 983.

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37. Braestrup, C., Nielsen, E.B., Sonnewald, U., Knutsen, L.J.S., Andersen, K.E., Jansen, J.A., Frederiksen, K., Andersen, P.H., Mortensen, A. and Suzdak, P.D.; **(R)-*N*-[4,4-bis(3-methyl-2-thienyl)-but-3-en-1-yl]-nipecotic acid binds with high affinity to the brain γ-aminobutyric acid uptake carrier**; *J. Neurochem*., **1990**, *54*, 639 - 647.

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42. Knutsen, L.J.S., Judkins, B.D., Mitchell, W.F., Newton, R.F. and Scopes, D.I.C.; **Synthesis of imidazo-fused bridgehead-nitrogen *C*-nucleosides *via* dehydrative coupling reactions of 2,5-anhydro-3,4,6-tri-*O*-benzoyl-D-allonic acid**; *J. Chem. Soc. Perkin Trans I*, **1984**, 229 - 238.

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