Curriculum Vitae

CHRISTOPHER J. SOARES, Ph.D.

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Leadership ~ Drug Discovery & Development ~ Expert Witness

Research scientist adept at utilizing experience within the biotech/pharmaceutical industry to successfully advance research and development objectives in diverse therapeutic areas. Proven ability to analyze scientific information and lead research programs.

- Biotech professional with extensive drug discovery and development expertise.
- Experienced with small molecule and macromolecular drugs (proteins and peptides) in multiple therapeutic areas. Extensive experience in peptide therapeutics based on the calcitonin and GLP-1 hormones with novel clinical candidates developed from both peptide families. This included dual acting analogues at both receptors and analogs with extended duration of action.
- Program leader for multidisciplinary teams (research, clinical, regulatory and development groups) who worked on projects aimed at advancing molecules to the clinic.
- Evaluated and implemented diverse technologies to enhance the delivery of drug candidates by various modes (nasal, oral, systemic, topical, etc).
- Currently advancing a peptide therapeutic for the treatment of neuropathic pain both as an acute therapeutic and an extended-release formulation for dosing as a once-weekly or oncemonthly treatment.
- Expert witness in a patent dispute between a pharmaceutical company and generic manufacturer. Case was settled the day preceding trial (May 2018 - March 2019).
- Scientific expert for the filing of an IPR of a GLP-1 agonist patent (2019)
- Expert witness for a generic pharmaceutical company challenging patents related to a peptide therapeutic used to treat symptoms of irritable bowel syndrome with constipation or chronic constipation (2021)

PROFESSIONAL POSITIONS

2013-present **AcheRx LLC,** Seattle, Washington. A peptide therapeutics company investigating diseases linked to the perception and transmission of neuropathic pain.

Scientific Founder – Discovered a novel series of peptide CGRP antagonists. Accomplished proof-of-concept studies resulting in the identification of a clinical candidate for the acute treatment of migraine. Patents obtained covering lead compound series and for novel methods-of-use. Received an SBIR grant to develop slow-release formulations of the peptide lead (August 2021)

2010-2013 **Avryll Therapeutics Inc.,** San Diego, California. A biotechnology company focused on the science of cartilage repair and biologic drug delivery.

Consulting R&D Director – Accomplished synthesis of drug substance and preclinical studies (*in vitro* and *in vivo*) towards the advancement of a clinical candidate. The budget was managed to reduce costs by over 40 % of initial estimates. Supervise collaborations, licensing agreements and intellectual property portfolio with external legal counsel.

2002-2010 **Amylin Pharmaceuticals, Inc.**, San Diego, California. A biotechnology company focused on discovering first-in-class medicines for metabolic disorders including diabetes and obesity.

Associate Director - Research (2005-2010)

- Managed groups of chemists in determining structure activity relationships and lead finding.
- Project co-leader for the identification and development of peptide candidates with increased duration of action (once-weekly) and oral bioavailability. Managed the design, evaluation *(in vitro*/*in vivo*) and nomination of candidates for clinical development.
- Evaluated novel compounds/biology for initiating therapeutic-area programs.
- As a team member helped to successfully:
  - Identify a clinical candidate for depression (Psylin Neurosciences Team).
  - Identify lead candidates for inflammation (BioSeek Collaboration).
  - Design moieties for synergistic weight loss (Phybrids for Obesity Team).

Sr. Scientific Investigator - Research Chemistry (2003-2005)

- Project co-leader for the identification and development of novel GLP-1 peptide candidates for the treatment of congestive heart failure. Peptides were designed to improve pharmaceutical properties *vs.* potency resulting in a pharmaceutically superior candidate chosen for clinical development.
- Initiated an effort to determine the synthetic feasibility of Phybrid peptides to incorporate dual pharmacologically active agents in a single moiety.
- Identified and advanced to clinical development a novel peptide that activated

Scientific Investigator - Research Chemistry (2002-2003)
Project co-leader for the identification and development of peptide candidates for the treatment of obesity. Peptides were designed to have increased efficacy and duration of action over the lead compound and resulted in the nomination of a clinical candidate currently in Phase II development.

1998-2002 **CombiChem Inc. /DuPont Pharmaceuticals Inc.** San Diego, California. A pharmaceutical company focused on developing computationally designed small molecule libraries and tools for high throughput synthesis and purification. CombiChem was later acquired by DuPont Pharmaceuticals Inc.

Senior Research Scientist - Medicinal Chemistry
Designed and synthesized novel compound libraries for partnership SAR project collaborations in Alzheimer's, cardiovascular, inflammation and obesity programs. Worked closely with computational groups to design and analyze library diversity.

1992-1998 **Amylin Pharmaceuticals, Inc.**, San Diego, California. A biotechnology company focused on discovering new medicines for metabolic disorders including diabetes and obesity.

Chemical modification of recombinantly produced peptides and accomplishing their stable formulation. Designed, synthesized and optimized leads of novel peptides, peptide mimetics and small molecule compounds for diabetes and obesity programs. Optimized both potency and synthetic procedures of several compound classes.

Senior Staff Scientist - Research Chemistry (1996-1998)
Staff Scientist - Research Chemistry (1993-1996)
Senior Research Associate - Process Chemistry (1992-1993)

1989-1992 The Scripps Research Institute, La Jolla, California. Postdoctoral Research Fellow in the laboratory of Prof. Reza Ghadiri, Department of Chemistry.

EDUCATION

Ph.D. Chemistry
University of California, Davis
Advisor: Dr. Mark J. Kurth

M.S. Chemistry
Hampton University, Virginia
Advisor: Dr. Charles M. Bump

B.Sc. Chemistry (Honours)
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PATENTS

1. **Soares, C. J.** "Use of CGRP receptor antagonists in neuroprotection and neurological disorders". US11390654B2. Filed: 08/30/2017, Granted: July **2022**
2. **Soares, C. J.** "CGRP agonist peptides". US9951115B2. Filed: July 2014, Granted: April **2018.**
3. **Soares, C. J.** "Peptide antagonists of the calcitonin/CGRP family of peptide hormones and their use". US9193776B2 Filed: Jan. 2013, Granted: Nov. **2015**
4. Forood, B. B.; Ghosh, S.; Trevaskis, J. L.; Sun, C.; Levy, O. E.; D'Souza, L. J.; **Soares, C. J.** "Polypeptide Conjugate". U.S. Pat. App. No. 13/511/201, accepted May 22, **2012.**
5. Samant, M. P.; D'Souza, L. J.; Levy, O. E.; Ghosh, S.; **Soares, C. J**. "Site-Specific Enzymatic Modification of Exendins and Analogs Thereof". U.S. Pat. App. No. 61/637,393, accepted April 24, **2012.**
6. Alfaro-Lopez, J.; **Soares, C. J**.; Coates, E.; Sharma, A.; Ghosh, S. S. "GLP-1 Receptor agonist compounds having stabilized regions". PCT/US2011/045614, published July 27, **2011.**
7. Ghosh, S. S.; Josue Alfaro-Lopez, J.; D'Souza, L. J.; Levy, O. E.; Lin, Q.; **Soares, C. J.** "Peptide-peptidase inhibitor conjugates and methods of making and using same". U.S. Pat. App. No. 2008077955, published February 4, **2008.**
8. Levy, O. E.; Baron, A. D.; D'Souza, L. J.; Erickson, M.; Ghosh, S. S.; Hanley, M. R.; Janssen, S.; Jodka, C. M.; Lewis, D. Y.; Mack, C. M.; Parkes, D. G.; Pitner, R. A.; **Soares, C. J.**; Srivastava, V.; Young, A. A.; Thao, L. DPP-IV Resistant GIP hybrid polypeptides with selectable properties" WO 2008/021560 published February 2, **2008**.
9. Ghosh, S. S.; Lewis, D. Y.; Janssen, S.; Srivastava, V.; Liu, Q.; Jodka, C. M.; **Soares, C. J**.; Lin, Q. "Composition and methods for treatment of congestive heart failure". International Pat. App. No. WO 2007/139941, published June 12, **2007.**
10. **Soares, C. J**.; Hanley, M. R.; Lewis, D. Y.; Parkes, D. G.; Jodka, C. M.; Prickett, K. S.; Ghosh, S. S.; Mack, C. M.; Lin, Q. "Amylin family peptides and methods for making and using them". International Pat. App. No. WO 2006/083254 A1, published August 10, **2006.**
11. Levy, O. E.; Hanley, M. R.; Jodka, C. M.; Lewis, D. Y.; **Soares, C. J**.; Ghosh, S. S.; D'Souza, L. J.; Parkes, D. G.; Mack, C. M. "Hybrid polypeptides with selectable properties". U.S. Pat. App. No. 20060094652, published May 4, **2006**.
12. Levy, O. E.; Hanley, M. R.; Jodka, C. M.; Lewis, D. Y.; **Soares, C. J**.; Ghosh, S. S.; D'Souza, L. J.; Parkes, D. G.; Mack, C. M.; Srivastava, V.; Janssen, S.; Baron, A. D.; Young, A. A.; Pittner, R. A.; Erickson, M. "GIP analog and hybrid polypeptides with selectable properties". International Pat. App. No. WO 2006/086769 A2, published Feb.10, **2006**.
13. Konradi, A.; Plies, M.A.; Thorsett, G.D.; Ashwell, S.; Sarantakis, D.; Welmaker, G.S.; Kreft, A.; Semko, C.; Sullivan, R.W.; **Soares, C.J**.; Ly, K.S.; Tarby, C.M. "Compounds which inhibit leukocyte adhesion mediated by VLA-4". U.S. Pat. App. No. 20050261293, published Nov. 24, **2005**.
14. Konradi, A.; Plies, M.A.; Thorsett, G.D.; Ashwell, S.; Sarantakis, D.; Welmaker, G.S.; Kreft, A.; Semko, C.; Sullivan, R.W.; **Soares, C.J**.; Ly, K.S.; Tarby, C.M. " Compounds which inhibit leukocyte adhesion mediated by VLA-4". U.S. Pat. No. 6,903,088, issued June 7, **2005**.
15. Konradi, A.; Plies, M.A.; Thorsett, G.D.; Ashwell, S.; Sarantakis, D.; Welmaker, G.S.; Kreft, A.; Semko, C.; Sullivan, R.W.; **Soares, C.J**.; Ly, K.S.; Tarby, C.M. " Compounds which inhibit leukocyte adhesion mediated by VLA-4". U.S. Pat. No. 6,479,492, issued Nov. 12, **2002**.

PUBLICATIONS

1. Levy, O.E.; Jodka, C.M.; Ren, S.S.; Mamedova, L.; Sharma, A.; Samant, M.; D'Souza, L.J.; **Soares, C.J**.; Yuskin, D.R.; Jin, L.J.; Parkes, D.G.; Tatarkiewicz, K.; Ghosh, S.S. Novel exenatide analogs with peptidic albumin binding domains: potent anti-diabetic agents with extended duration of action. *PLoS One*, **2014**, *9*, 0087704
2. **Soares, C**.; Mack, C.; Ghosh, S.; Lewis, D.; Lin, Q.; Lwin, A.; Herich, J.; Pittner, R.; Wilson, J.; Roan, J.; Alvarado, L.; DeConzo, K.; Jodka, C.; Guss, S.; Laugero, L.; Gedulin, S.; Smith, P.; Hanley M.; Parkes D. "Davalintide (AC2307), a Novel Amylin Mimetic Peptide: Enhanced Pharmacological Properties Over Native Amylin to Reduce Food Intake and Body Weight". *Int. Journal of Obesity*, **2010,** *34*, 385.
3. Alfaro-Lopez, J.; **Soares, C. J**.; Ghosh, S. S.; Kravchuk, A.; Coates, E.; Jodka, C. M.; Carroll, A; and Lin, Q "Peptide-Lisinopril Conjugates: Design, Synthesis and Biological Activities". *Advances in Experimental Medicine and Biology*, **2009**, *611*, 535.
4. Roth, J. D.; Mack, C. M.; **Soares, C. J**.; Ghosh, S. S.; Parkes, D. G. Amylin-Based Pharmacotherapy – Past, Present and Future. Immun. Endoc. & Metab. Agents in Med. Chem., **2008**, *8*, 317-324.
5. Saiah, E.; **Soares, C**. "Small molecule coagulation cascade inhibitors in the clinic". *Curr. Top. Med. Chem.* **2005**, *5,* 1677-95.
6. Prickett, K.S.; Albrecht, E.; **Soares, C.J**.; Lumpkin, R.H.; Gaeta, L. S. L.; Moore, C.X.; Young, A. A.; Beeley, N.R.A.; Beaumont, K. **1995**. "Design of receptor selective peptides that antagonise the action of amylin *in vivo*". Proceedings of The Fourteenth American Peptide Symposium.
7. Ghadiri, M.R.; **Soares, C.J**.; Choi, C. "Design of an artificial four-helix bundle metalloprotein *via* a novel Ru(II)-assisted self-assembly process". *J. Am. Chem. Soc.* **1992**, *114*, 4000.
8. Ghadiri, M.R.; **Soares, C.J**.; Choi, C. "A convergent approach to protein design. Metal ion assisted spontaneous self-assembly of a polypeptide into a triple helix bundle protein". *J. Am. Chem. Soc.* **1992**, *114*, 825.
9. Reddy, G.N.; **Soares, C.J**.; Kurth, M.J.; Segall, H.J. "Use of 2-Dimethylaminopyridine in tritium and deuterium exchange reactions". *J. Labeled Cmpds and Radiopharm.* **1991**, *29*, 1257.
10. Kurth, M.J.; **Soares, C.J**. "Asymmetric aza-Claisen Rearrangement: Synthesis of (+)dihydropallescensin-2[(+)-penlanpallescensin]". *Tetrahedron Lett.* **1987**, *28*, 1031.