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At Wake Forest School of Medicine in Winston-Salem, NC, Dr. Atala serves as the Director of Wake Forest Institute for Regenerative Medicine, the world's largest such facility. At the Institute, he and his staff are currently growing over 30 different tissues, from heart valves to muscle to livers. With more than 25 years of experience, his main research focus is growing human tissues and organs to replace those damaged by disease or defect, and he led the team that developed the first lab-grown organ to be implanted into a human. Along with his ground-breaking research, Dr. Atala is a practicing surgeon and Chair of the Department of Urology at Wake Forest University. He is also a long-standing member of the STEM CELLS Editorial Board.

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A New Era in Stem Cells Translational Medicine

ANTHONY ATALA

Thirty years ago this month, a landmark event occurred in the field of stem cells: the first journal dedicated to this special area of interest was started, and appropriately titled STEM CELLS. AlphaMed Press, a new publisher with an uncanny ability to see the future, was born out of necessity, and a newborn birth it was. For at the time, the field of stem cells was not even in its early infancy, but rather in its early embryonic development. Only a handful of investigators led the way to what the field would become today, and few could have predicted then what was to come. An inquiry now with the term "stem cell" in the PubMed search engine shows a total of approximately 200,000 published articles dealing with dozens of stem cell types. Our understanding of the basic biology for many of these cells is still far from complete, yet advances are being made daily.

Today, a new era dawns on the field. The potential of stem cells therapies and regenerative medicine is both provocative and powerful, offering the distinct possibility of eventually repairing or replacing tissues damaged from disease, including certain cancers. The major body of scientific work performed in tens of thousands of laboratories worldwide is slowly giving way to clinical translation. However, the path is not easy, and like any transition, there are fits and starts. The field promises to make great gains, but the challenges are real. Appropriate preclinical models and assays, the use of small molecules, the influence of genomics on outcomes, mostly uncharted use of cells in humans, dozens of clinical applications, cell viability and potency requirements, manufacturing challenges, long-term therapeutic and safety effects, regulatory trends, clinical trial designs, and clinical delivery models are just a few of the areas that need constant study, exploration, and improvement. As advances in our understanding of the field keep moving forward, more cell types and applications are being used in patients. It is only fitting then to have a journal that would serve as the forum for these types of advances in the field of cell therapy, a journal that would not only publish the most relevant papers but also attempt to keep an accurate pulse on the people and events that may influence the direction of the field. A term that best describes the transition

from the bench to the bedside, and the process by which this occurs, is translational medicine. We, therefore, welcome and celebrate the formation of: STEM CELLS TRANSLATIONAL MEDICINE. This exciting new journal will foster the proper growth and ethical development in this fast-moving field. As the sister journal to STEM CELLS, STEM CELLS TRANSLATIONAL MEDICINE will bridge the gap in the existing stem cells journal spectrum, and together they will elevate the science to applications that will help the lives of many people.

We are fortunate to have assembled a group of stellar scientists for the Editorial Board. The Associate Editors and members of the Editorial Board, all leading experts, are committed to the advancement of the field and the mission of this journal: STEM CELLS TRANSLATIONAL MEDICINE is dedicated to significantly advancing the clinical utilization of stem cell molecular and cellular biology. By bridging stem cell research and clinical trials, the journal will help move applications of these critical investigations closer to accepted best practices.

The journal is dedicated to publishing original articles and reviews related to the clinical translation of all types of stem cell, cell, tissue engineering, and regenerative medicine therapies. The journal will also publish papers with topic areas relevant to the process of translation, including cell-based drug development, screening, and toxicology; enabling technologies; standards, policies, and regulations; and protocols and manufacturing for cell-based clinical translation and therapies. First-in-human reports will be highlighted. The News section in the journal will draw attention to important breaking stories impacting the field. Profiles of individuals and institutions will help the reader keep abreast of current concepts and changing trends. A section on Perspectives will highlight interesting informational and opinion pieces from invited authors.

This first issue of the journal has two very timely opinion pieces. Alan Trounson, Director of the California Institute for Regenerative Medicine (CIRM), Natalie DeWitt, Special Projects Officer at CIRM, and Ellen Feigal, Vice President for Research and Development at CIRM, report on the topic of what may be needed for an effective stem cell clinic model. The second opinion

piece is from Mahendra Rao, just recently appointed as the first director of the National Institutes of Health's (NIH) new Center for Regenerative Medicine, and NIH Director Francis Collins, whose new initiative in the intramural program is now a national priority.

Several organizations and individuals have been instrumental in the birth of this new journal. We are grateful to have the commitment and support of several organizations, including the California Institute for Regenerative Medicine and Quintiles. We are also very fortunate that AlphaMed Press, and its managing staff, under the leadership of Marty and Ann Murphy, have once again expressed their visionary leadership in the stem cell field with the formation of this new journal, yet another pioneering publishing effort.

The U.S. Department of Health and Human Services (HHS), in its report, "2020: A New Vision—A Future for Regenerative Medicine," calls regenerative medicine the "next evolution of medical treatments." As the next evolution of medical treatments develop, it is imperative that the dissemination of information be accurate and rapid. By helping speed expertly executed translations of emerging lab discoveries into legitimate clinical trials and bedside application, STEM CELLS TRANSLATIONAL MEDICINE ultimately will help to improve patient outcomes.

Anthony Atala, MD

STEM CELLS
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First-in-Human Case Studies CALL FOR PAPERS

The potential of stem cell therapies and regenerative medicine is provocative and powerful. By helping speed expert translations of emerging lab discoveries into legitimate clinical trials and bedside application, STEM CELLS TRANSLATIONAL MEDICINE ultimately will improve patient outcomes.

STEM CELLS TRANSLATIONAL MEDICINE welcomes original articles and concise reviews describing the clinically relevant translational aspects of stem cells and progenitor cells for cell-based therapy, tissue engineering and regenerative medicine from the bench to patient care.

Particularly, we are seeking:

First-in-Human Case Studies

These manuscripts should include human case studies that show the state of the field and related challenges.

Some of the considerations to include are:

- Compelling preclinical rationale and proof of concept.
- Novel approaches using regenerative medicine tools and therapeutics.
- Novel approaches of combinatorial regenerative medicine therapeutics.
- Safety and preliminary efficacy data
- Early phase II and phase III studies that report an unusual clinical response or an unexpected adverse effect.
- Convincing safety and tolerability of the regenerative medicine approach.

Submissions are limited to one page and one figure.

More details on submission expectations and process are available at:
www.StemCellsTM.com

Send pre-submission inquiries to: Editor@StemCellsTM.com.